UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE GENZYME CORP. SECURITIES LITIGATION	Consolidated Case No. 09-cv-11267 (GAO)

LEAD PLAINTIFFS' COMBINED MEMORANDUM OF LAW IN OPPOSITION TO GENZYME CORPORATION'S AND THE INDIVIDUAL DEFENDANTS' RESPECTIVE MOTIONS TO DISMISS

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PRELIMINARY STATEMENT

Plaintiffs bring this action on behalf of themselves and a class of investors (the "Class") who purchased securities of Genzyme Corporation ("Genzyme" or the "Company") between October 24, 2007 and November 13, 2009 (the "Class Period"), at prices that were artificially inflated by fraudulent statements and omissions by Genzyme and its six top executives.[1]

Like any pharmaceutical company, Genzyme's success depends on its ability to manufacture safe, reliable, and effective drug products. As the Complaint details, however, Genzyme's flagship Allston, Massachusetts plant (among other Company facilities) was plagued by an array of pervasive problems throughout the Class Period. These problems included myriad basic deficiencies in the equipment and procedures required to ensure that Genzyme's drugs were produced in a safe, sterile, and contamination-free manner, and constituted serious violations of Current Good Manufacturing Practices ("CGMP") mandated by U.S. Food and Drug Administration ("FDA") regulations. Indeed, they were so severe that they led to unprecedented multiple viral outbreaks, multiple warnings and related notices from the FDA, plant shutdowns and, eventually, yet another serious contamination outbreak, an FDA Consent Decree and a $175 million fine. Regrettably, despite their knowledge concerning the Company's true condition, Defendants chose to *conceal* adverse information for as long as possible.

Conditions at Allston in particular were highly material to investors, both because it was where Genzyme produced the medicines responsible for roughly 50% of its annual sales, and because it was the designated site for the manufacture of a mass-producible version of its highly profitable Myozyme product. Although Genzyme had applied for FDA approval of this product

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[1] The individual officer defendants are Henri Termeer ("Termeer"), Genzyme's Chairman, President and CEO; Michael Wyzga ("Wyzga"), its CFO; David Meeker ("Meeker"), its Executive Vice President; Allison Lawton ("Lawton"), SVP for Regulatory Affairs; Mark Bamforth ("Bamforth"), SVP for Corporate Operations and Pharmaceuticals; and Geoffrey McDonough ("McDonough"), SVP and head of Genzyme's Personal Genetic Health unit (collectively, the "Individual Defendants," and together with Genzyme, the "Defendants").

variant (known as "Lumizyme"), FDA regulations required the plant where Lumizyme was to be manufactured (Allston) to be CGMP-compliant before any such application could be approved. But despite their obvious importance, Defendants did not timely disclose the breadth or depth of the problems plaguing Allston. Instead, they repeatedly assured investors that Lumizyme was on track for early approval, and made glowing positive statements about Genzyme's business and operations. Defendants also misled investors during a significant part of the Class Period when they told them to expect revenue from commercial-scale U.S. production of Lumizyme, after the Company had secretly decided in early March 2009 to *abandon* plans for any such production.

It was not until well into the Class Period that Defendants finally began to partially disclose the existence of *some* deficiencies at Allston. Even then, they only disclosed limited information in a piecemeal fashion, while giving false assurances that any compliance issues had been (or were nearly) fixed, and that they posed no threat to Genzyme's ongoing operations or to its pending application for FDA approval of Lumizyme. As a result, even as Genzyme's stock price fell in response to a series of partial disclosures of compliance woes, it continued to trade at artificially inflated levels until November 13, 2009, when the FDA rejected the Company's Lumizyme application and issued a public health advisory warning physicians of serious health risks caused by yet *another* drug contamination outbreak at Allston.

Events over the following weeks and months, including statements by Defendants themselves, only confirmed the extent to which they had concealed information concerning the full nature and extent of Genzyme's compliance problems. Only after the Class Period did investors learn that Defendants had actually admitted to the FDA *during* the Class Period that the problems at Allston were "fundamental" and "systemic." Ultimately, in May 2010, the FDA ran out of patience with Defendants' repeated false assurances of prompt remedial action at Allston, and filed a preliminary injunction complaint against Genzyme and defendant Termeer. In response, Genzyme and Termeer entered into a Consent Decree, under which the Company agreed, *inter alia*, to (1) pay a $175 million disgorgement penalty for past compliance violations

at Allston; (2) appoint an outside monitor to oversee the Allston plant; and (3) implement an adequate remediation plan. Tellingly, in contrast to Defendants' repeated assurances during the latter half of the Class Period that Genzyme was able to quickly remedy any FDA compliance concerns, Genzyme has since stated that it will likely take ***2-3 years*** to implement such a plan.

Defendants seek dismissal on various grounds to avoid liability for the losses that their fraud has inflicted on Genzyme's investors. As set forth below, their motions should be denied.

STATEMENT OF FACTS

A. Genzyme's Core Business, and the Key Importance of its 2000L Myozyme (a/k/a Lumizyme) BLA

Genzyme's principal line of business is its Genetic Diseases Segment, which produces drugs used primarily to treat rare conditions (known as lysosomal storage diseases, or "LSDs") associated with the absence of particular enzymes. ¶¶36, 41.[2] Genzyme's three main products in this area, which generated roughly half of its annual sales, were:

- ***Cerezyme***, which is a treatment for Gaucher disease and at all relevant times was Genzyme's top selling product, with almost $1.2 billion in sales in 2008;
- ***Fabryzyme***, which is a treatment for Fabry's disease and at all relevant times was Genzyme's third best-selling product, with almost $500 million in sales in 2008; and
- ***Myozyme***, which is a treatment for Pompe's disease. From 2006 when it was launched, Myozyme quickly became Genzyme's fastest growing product line, with sales of roughly $59 million in 2006 quintupling to $296 million in 2008.

¶¶37-39. These products are classified as "biologics" rather than "drugs" because they are composed of living biological organisms. *Due to the living nature of the product, biologics are far more susceptible to contamination than traditional drugs.* As a result, anti-contamination practices are particularly important with respect to the manufacture of biologics. ¶35

Prior to the Class Period, Genzyme decided that it could not produce adequate quantities of Myozyme at its existing 160 liter batch production scale. Accordingly, it developed a process to manufacture a variation of Myozyme, called "Lumizyme," that could be produced in much

[2] Citations herein to "¶__" are to paragraphs of the Consolidated Class Action Complaint.

larger 2000 liter ("2000L") batches. Genzyme obtained approval of Lumizyme from European authorities, and began to manufacture it at Allston for sale in Europe. Because of differences in the manufacturing processes for Lumizyme as compared to 160L Myozyme, however, Genzyme needed separate FDA approval to sell the 2000L product in the U.S. ¶¶48-50.

The early response to the introduction of Lumizyme in Europe confirmed its importance to the Company's ability to generate revenue growth, as sales of 2000L Myozyme (*i.e.*, Lumizyme) quickly outstripped sales of 160L Myozyme. As defendant Termeer noted in July 2008, *by mid-2008 roughly 90% of Genzyme's Myozyme-related revenues were attributable to the 2000L product (Lumizyme).* ¶51. Accordingly, financial analysts and investors considered the Lumizyme application for FDA approval – in the form of a biologics license application ("BLA") – and the related expansion of the U.S. market for Myozyme-based drugs, to be of key importance. *As one analyst noted in February 2009, "at the end of the day, what moves the needle of growth for Genzyme is Myozyme[-Lumizyme]."* ¶52.

B. The Critical Importance of Genzyme's Allston Facility

Because of limitations at its Framingham, MA plant, in 2005 Genzyme decided to house its U.S. Lumizyme production at its Allston plant. Originally built in 1994 to produce Cerezyme, Allston had also begun to manufacture Fabrazyme in 2002. With the transfer of Lumizyme production to Allston in 2006, the Allston plant effectively became the ***sole*** site for manufacturing the drugs that accounted for roughly half of Genzyme's annual sales, including the three most important drugs in its core Genetic Disease business. ¶¶53-54.

C. The Extraordinary, Serious and Pervasive Undisclosed Problems That Plagued Genzyme And Its Flagship Allston Facility During the Class Period

As a pharmaceuticals manufacturer, all of Genzyme's production facilities are required by FDA regulations to comply with "current good manufacturing practices" ("CGMP"). *See* 21 C.F.R. §§ 210, 211. CGMP require Defendants, among other things, to maintain and follow detailed, formal procedures for all aspects of the manufacturing process. *FDA regulations*

explicitly make senior management responsible for ensuring compliance with CGMP. ¶44. Pharmaceutical products manufactured in violation of CGMP are considered "adulterated," subjecting the offending company to required regulatory action by the FDA. CGMP compliance is not only required for existing drug products, it is ***also*** an essential requirement for FDA approval of a new drug BLA – and the FDA will not approve a new drug BLA if the plant in which the drug is to be manufactured is not operating in accordance with CGMP. ¶¶42-44.

Throughout the Class Period, however, Genzyme was plagued by a host of pervasive, systemic and severe CGMP compliance deficiencies – especially at its key Allston plant. These problems seriously threatened Genzyme's ability to produce Cerezyme and Fabrazyme, as well as its ability to obtain FDA approval of Lumizyme. As Plaintiffs allege, these problems were the byproduct of a *culture of noncompliance* at Genzyme in general (and at its critical Allston facility in particular), as well as Defendants' decision to run the overburdened Allston plant at "over 100% capacity." ¶¶55-56. Genzyme's rampant CGMP violations, which permeated nearly every aspect of its Allston facility during the Class Period, are summarized below.[3]

1. Failures to Implement Necessary Practices and Procedures To Prevent Contamination of Drugs Produced at Allston

As the FDA would later find, Genzyme failed to implement even basic practices and procedures at Allston to ensure a sterile production environment and to prevent contamination of its drug products. Key deficiencies included:

(a) Defective Airflow Sterilization Practices: Sterile airflow is essential to the sterile manufacture of biologic drug products because particles and microbes in the air can contaminate the medicine. At Allston, however, Genzyme's practices and procedures for testing the sterility of airflows were patently inadequate – and even when its inadequate procedures did

[3] As the discussion below shows, Genzyme's repeated assertions (Genzyme Br. 9, 30) that its compliance problems (and the FDA's concerns regarding the same) were limited "only" to "fill/finish" operations at Allston is simply false. Although deficiencies in the fill/finish area were significant, they were only part of a broader constellation of fundamental and systemic deficiencies that included improper sterilization and decontamination practices, inadequate training, improper handling of raw materials, "in-process" production deficiencies, and a general culture of noncompliance.

detect problems with the plant's airflow Genzyme failed to take appropriate corrective action. For example, Genzyme tests conducted in April 2006, August 2007 and January 2009 all failed to demonstrate proper airflow, yet no corrective action was undertaken. ¶60. Moreover, as Genzyme's metrology manager told the FDA during a 2009 inspection, no documentation existed to show that required air testing in various locations within the plant had *ever* been performed, in violation of Genzyme's own written procedures. ¶¶59-60.

(b) Defective Cryoshippers and Cryoshipping Practices: Cryoshippers are special containers used to transport biologic material in a frozen state. They are essential to Genzyme's operations because they are used to transport live cells (used to produce its drugs) between its raw materials "hub" at Framingham and its production facilities at Allston and Geel, Belgium. Proper use of cryoshippers was thus vital to ensuring that these raw materials, and Genzyme's end products, were free of serious contamination and degradation problems. Nonetheless:

- Genzyme's facilities (including Allston) routinely relied upon aging cryoshippers manufactured in 2002 and 2003 and that had a life expectancy of only five years, yet Genzyme continued to use them well into 2009;
- Genzyme never validated its cryoshippers to confirm they were functioning properly, and never performed maintenance on them for the entire time they were in use – even as the cryoshippers continue to be used well past their five-year life expectancy; and
- Genzyme routinely utilized cryoshippers in ways contrary to their appropriate use and in violation of their operating instructions, thereby drastically reducing their ability to keep their contents frozen. ¶61.

(c) Additional Serious Deficiencies in Sterile Practices and Procedures: As set forth in greater detail in the Complaint (at ¶62), Genzyme's numerous violations of other, basic anti-contamination practices and procedures included:

- failure to monitor the amount of microbiological contamination (bacteria, spores, or other organisms) during the manufacturing process;
- failure to determine whether Allston's internal limits for the presence of microbiological contaminants were set at proper levels;
- failure to use disinfectants that were adequate to eliminate various microorganisms (even though this problem had been documented as early as 2005);

- failure to document the rationale for its haphazard selection (or non-selection) of various locations to test for microbial contamination, and inability to determine the sources of contamination by microorganisms even when detected;

- failure to maintain filters necessary to prevent contamination in hoses used to deliver liquid drug substances to the filling area (where the product is placed into vials);

- failure to adequately seal observation windows overlooking Allston's purportedly sterile filling operations;

- failure to test protective gear for sterility;

- failure to prevent contact between personnel wearing protective gear and personnel dressed in unsterile street clothes; and

- failure to keep *any* records to establish that it sterilized its manufacturing equipment or much of the equipment and tools used during the sterile filling process at Allston.

As shown in FDA reports, Genzyme was also in violation of numerous additional CGMP requirements that directly threatened the purity of the drugs made at Allston. For example, measurements of particulate matter were taken in the wrong locations in key production rooms, and although FDA inspectors could actually ***see*** particles floating in air ducts at Allston, Genzyme personnel could not identify whether they were coming from a "sterile" area or otherwise identify their source. ¶68. Other serious deficiencies included:

(d) **Deficient Filling Line Practices:** The processes used to operate the filling lines at Allston (where empty vials are filled with the finished medicinal products) were defective in numerous ways, greatly increasing the risk that medicines filled on these lines would be contaminated with metallic and other particles. Among other things:

- the filling lines had been installed in 1994 and had never been calibrated;

- metal shavings from the obsolete filling lines contaminated the products;

- Genzyme regularly ran Allston's filling lines at improperly high speeds, frequently causing the lines to jam and necessitating manual intervention, which introduced yet another source of potential contamination into the manufacturing process;

- Genzyme continued to operate the lines at unsuitably high speeds and failed to conduct any tests to determine the impact on the final product, even after the FDA specifically brought this problem to the Company's attention. ¶65.

(e) **Inadequately Maintained and Contaminant-Producing Chromatography Columns:** A "chromatography column" is a device that uses chemicals to separate pure drug product from impurities, and is thus critical to the drug purification process. Allston's chromatography columns, however, were prone to "rouging," *i.e.,* developing iron deposits (such as rust). According to a former Allston technician (CW#2), rouging had *always* been a serious issue at Allston, and Allston employees would regularly see chips of rouge floating in water used in the chromatography process. Nonetheless, CW#2 stated that Genzyme had no program to address the problem (a statement confirmed by the FDA's own later finding in October 2008 that Genzyme had *never* performed any maintenance on the columns). In addition, the computer system that calibrated chemical substances used by the columns in purification had been improperly programmed *since 1999*, and had never been updated or even reviewed for errors. As a result, the chemicals used in the columns were not properly formulated to effectively perform the purification. Even after Genzyme promised the FDA in late 2008 to implement corrective procedures for the chromatography columns, it failed to do so. ¶65.

(f) **Inadequate Procedures for Final Inspections:** Genzyme's practices and procedures for inspecting its final products for particulate contamination, discoloration and/or damage to finished product vials were also riddled with glaring deficiencies. For example:

- Genzyme frequently received complaints from third parties about foreign substances in products prepared and approved by visual inspection in Allston, yet it failed to identify the source of the contamination or to take any corrective measures;

- Genzyme failed to provide proper training to personnel responsible for performing necessary inspections; *e.g.,* those employees were trained and qualified on products that were *different* from the ones that they were actually responsible for inspecting;

- Even when quality control issues were identified, relevant procedures were often plainly deficient. For example, although Allston set limits on how many drug vials could be found to be contaminated before an investigation would be triggered, the Quality Assurance ("QA") unit only considered contaminants detected in an *initial* round of visual inspections. Thus, if later inspections detected further contamination that caused total contaminant levels to exceed the limit, *no* investigation would occur;

- As the FDA pointed out, inspections at Genzyme's facilities in Japan regularly identified contamination in products that Allston had inexplicably approved; and

- Genzyme failed to document how much time Allston employees spent on inspection shifts, making it impossible to determine whether shifts exceeded maximum time limits – thereby greatly increasing the risk of human error in visual inspections. ¶67.

(g) Deficient Purification Practices: Genzyme also failed to follow critical purification protocols, especially with respect to the manufacture of Cerezyme at Allston. For example, Genzyme regularly reused certain filters to purify Cerezyme, without ever determining whether they could be reused safely. Moreover, various chemicals used in the purification process were also formulated improperly, and Genzyme lacked effective controls to ensure that these chemicals had the proper composition, and that they did not degrade during use. ¶¶70-71.

(h) Allston's Entirely Inadequate Quality Assurance Systems: CGMP requires a drug manufacturing facility to have an independent quality control department that oversees and ensures the safety of the production process. However, at the overburdened Allston facility, Genzyme's QA program was in complete disarray, to the point where activities performed during the manufacturing process had not even been authorized by QA. As Genzyme's Vice President of Quality Operations would later admit to the FDA, Allston had no standard procedures setting forth the types of reviews that its QA department needed to perform, and it never implemented any program to assess (let alone prevent or remedy) systemic problems at the plant. ¶72.

In addition, Genzyme's QA department routinely failed to conduct proper investigations of actual or potential problems, as it often failed to initiate appropriate investigations and/or simply dropped ongoing inquiries prior to completion. ¶¶67, 73 (citing numerous examples). Further, various steps were taken at Allston to evade QA tests and improperly limit the role of the QA department in monitoring manufacturing. For example, in several test runs intended to properly validate the sterile filling process during 2008 and 2009, Allston personnel removed and discarded specific vials from the filling line before they could be tested, thus making it impossible for the QA department to determine if the sterile fill process was in fact sterile. ¶74.

(i) Mishandling of Raw Materials: In addition to its improper use of cryoshippers (*see* §1(b) above), Allston's other procedures for handling raw materials were also riddled with CGMP violations. For example, (i) raw materials were not properly tested and sampled; (ii) Allston failed to track substandard raw materials, making it impossible to determine if any particular supplier posed a systematic contamination risk; and (iii) raw material inspection requirements were not modified in response to raw material failures. ¶75. Similarly, as CW#2 confirmed, Genzyme failed to keep proper samples of raw materials it received from outside sources – a critical defect that impaired Genzyme's ability to identify the source of any problems that later arose. ¶76; *see also* §2, *infra*.

(j) Seriously Inadequate Training of Key Allston Personnel: Allston's employees lacked adequate training in numerous critical aspects of CGMP compliance. For example, (i) as noted at §1(f) above, employees regularly performed QA inspections without proper training (¶67); (ii) when Allston employees failed to follow proper procedures, including with respect to anti-contamination procedures), Genzyme failed to require retraining, and maintained no records reflecting any investigations into the reasons for its employees' failures (¶77); (iii) in violation of written procedures requiring recertification, operators on Allston's filling line (a key part of production) were frequently not requalified for years (*id.*); and (iv) despite its repeated assurances to the FDA that it would establish "rigorous" training programs for fill line procedures, Genzyme *never* created any such training program. *id.* Indeed, as CW#3 (a senior technician at Allston during the Class Period) confirmed, Genzyme regularly hired individuals to work in compliance and production-related positions who lacked appropriate backgrounds in biology or other relevant disciplines; instead, to avoid having to pay the higher salaries that qualified personnel would require, Genzyme regularly hired persons with no relevant qualifications, such as auto mechanics and truck drivers. ¶78. Placing such unqualified persons in compliance positions was in direct conflict with CGMP. *See* ¶78 (quoting 21 C.F.R. § 600.10).

(k) Additional CGMP Compliance Deficiencies That Jeopardized The Sterility Of Drugs Produced At Allston: Allston also suffered from numerous other serious CGMP deficiencies that threatened the sterility of the plant and the purity of its products, including:

- Failure to perform routine validation procedures on plant equipment. For example, in addition to failing to validate filling line speeds, in 2003 Genzyme refitted the machinery used to freeze-dry drugs produced at Allston, but never performed basic tests to ensure its proper operation, causing errors in the freeze-drying process (¶79);

- Failure to update Allston's written standard operating procedures when practices were discontinued or modified. For example, the actual written procedures meant to be followed by Allston personnel were often not available to Genzyme employees responsible for carrying out the relevant processes, nor could compliance with them be reliably assessed (¶80); and

- Failure to maintain basic records was woeful. For example, in addition to other examples noted earlier, Genzyme did not maintain basic container and labeling records for products produced at Allston, and failed to keep proper records of the active ingredients in those medicines (with the result that it could not establish whether its medicines had been properly formulated with the correct amount of such ingredients) (¶81).

2. Additional Serious Compliance Problems Beyond Allston

Significantly, the deficiencies at Allston were only further exacerbated by a variety of serious CGMP violations at Genzyme's raw materials "hub" at Framingham. For example:

- Framingham also failed to test for air quality and particulate contamination (¶82);
- Framingham personnel also failed to wear full-body protective gear to ensure sterility, and non-sterile persons frequently "poked their heads" into the plant's supposedly sterile areas without protective gear (id.);
- Framingham personnel also lacked adequate training in sterile procedures (id.);
- According to a former Quality Control analyst at Framingham (CW#5), Genzyme supervisors directed that raw materials samples at Framingham be tested multiple times until they achieved the desired results, and then caused documents reflecting the earlier (and unsatisfactory) test results to be shredded (id.); and
- In violation of CGMP, instead of receiving training from "qualified individuals on a continuing basis," Framingham lab workers were told to train themselves, or to seek help if they felt they needed it; in addition, and also in violation of CGMP, records of tests performed for training purposes were not preserved, and thus Genzyme lacked documentation that its employees were proficient in their assigned tasks. Id.

Ultimately, at the end of the Class Period, Genzyme was forced to revamp its quality control procedures at Framingham as well as at Allston. *Id.*

3. Summary

In sum, as Defendants would later admit, the Allston plant, with its rampant CGMP deficiencies and aging equipment, was simply not capable of handling the increased burden of manufacturing Lumizyme in addition to Cerezyme and Fabrazyme. Instead, by the start of the Class Period, the mix of grossly deficient practices and procedures, inadequate training and aging equipment, combined with increased Myozyme and Lumizyme production demands, was an obvious recipe for disaster that posed grave (but undisclosed) risks for both Genzyme's patients and its investors. ***As Termeer would later admit, "We put too much stress on the plant. We ran it 24 hours a day, over 100% capacity."*** Similarly, as defendant Meeker admitted at the end of the Class Period – after the FDA had already issued at least two Form 483's and a warning letter regarding the problems at Allston – the issues identified by the FDA were ***"not new"*** and were matters that ***"we were very aware of*** and were working to address." ¶88.

Defendants eventually made partial disclosures of the existence of some of these problems during the latter part of the Class Period. As discussed below, however, even their belated partial disclosures were coupled with patently false and misleading assurances that the problems had been (or were being) fully and adequately addressed, and that the Lumizyme BLA (which could only be approved if Allston was CGMP-compliant) remained on track. ¶89.

D. Class Period Events

1. The Fraud Begins

On October 24, 2007, the first day of the Class Period, defendants Termeer, Meeker and Wyzga participated in an investor conference call. During the call, they assured investors that Genzyme's plans to obtain FDA approval to manufacture Lumizyme at Allston in 2008 were on track, that the picture for Myozyme/Lumizyme was "very, very positive," and that Genzyme saw little threat to Cerezyme, its top-selling drug, from any competing products given the very long-

term "extremely solid experience that we have around Cerezyme." ¶¶90-91, 216-19. Over the next 12 months (October 2007 to September 2008), Defendants, while noting their obligation to maintain compliance with CGMP, similarly continued to assure investors that Allston "contain[ed] extensive sterile filling capacity," and that Genzyme (a) was "positioned well" for 2008, (b) was being "continuously manage[d] toward sustainable growth," and (following the FDA's April 2008 decision to require a separate BLA for Lumizyme[4]) (c) fully expected to receive approval for Lumizyme in late 2008. ¶¶223-241.

As the Complaint alleges, however, these repeatedly positive public statements conspicuously failed to even hint at – let alone disclose – any of the Company's compliance problems, the inability of the aging Allston plant to support yet another major production line (for Lumizyme), or the extent to which Genzyme's ability to supply Cerezyme and Fabrazyme was jeopardized by Defendants' conscious decisions to place even greater demands on an already overburdened Allston plant. ¶¶220, 227, 229, 231, 236, 241-43.

2. Two Viral Outbreaks, and the Damning October 2008 Form 483

In September 2008, Genzyme's new plant at Geel, Belgium (where 4000L Myozyme, which was not approved by the FDA, was manufactured for sale in Europe) suffered a contamination outbreak of a virus strain known as Vesivirus 2117. This type of contamination is extremely rare, having occurred only once before (15 years earlier) in a pharmaceutical manufacturing facility. However, even though the biologics industry had known since that outbreak 15 years earlier the high degree of control and compliance required to avoid a Vesivirus 2117 contamination outbreak – and even though Defendants were presumably on heightened alert after the Geel outbreak to avoid any similar contamination problems at Genzyme's U.S. facilities – just two months later (in November 2008) Genzyme experienced an unprecedented ***second*** outbreak of the same viral contamination, this time at its flagship Allston plant. ¶¶95-96.

[4] Genzyme initially sought approval of Lumizyme as part of a supplemental BLA ("sBLA") to its already approved BLA for 160L Myozyme. The FDA, however, later concluded that processes used to make the 160L and 2000L products were sufficiently dissimilar to require a full BLA for Lumizyme. ¶¶50, 92.

These outbreaks caused production at both Geel and Allston to slow considerably. As a result, Genzyme was forced to (a) write-off millions of dollars of in-process medicines at Geel (which it falsely told investors was part of ordinary plant start-up costs), and (b) draw down its 2000L inventories (thus contributing to what Defendants would describe as "tight" Lumizyme and Myozyme supply in 2009). Incredibly, however, Defendants concealed both viral outbreaks (and their effects on Myozyme supply) from the public until June ***2009*** – and also continued to conceal Genzyme's myriad CGMP problems and culture of non-compliance. ¶¶97, 104-05, 245.

At around the time of the viral outbreak at Geel, during September and October 2008, the FDA inspected the Allston plant. The inspections identified at least 16 serious deviations from CGMP, as reflected in a "Form 483" issued on October 10, 2008. A Form 483 is the FDA's formal post-inspection report and is reserved for communicating only "***significant***" violations detected during an inspection; ¶46. The significant violations identified included:

- use of cryoshippers (which were used to ship raw materials) well beyond their life expectancy, failure to perform required maintenance on them, and failure even to have them properly validated;
- failure to monitor the amount of microbiological contamination on in-process material and chemical purification agents during purification;
- rouging on the chromatography columns, and lack of proper maintenance thereof "in that they have ***never*** been maintained";
- failure to properly test the HVAC ("heating, ventilating, and air conditioning") system, including failure to demonstrate "critical aseptic functions" and failure to undertake "active viable air sampling;"
- failure to properly monitor the composition of chemical agents used for purification;
- operation of fill lines at improperly high speeds, causing equipment malfunction; and
- inability to document whether numerous types of compliance actions had been taken.[5]

[5] The foregoing is only a partial listing of the serious adverse findings in the October 2008 483. For a more complete listing of the problems identified in the October 2008 483, *see* Complaint ¶99.

Defendants, however, deliberately chose ***not*** to disclose either the October 2008 483 or the two Vesivirus contamination outbreaks until much later in the Class Period. Instead, in response to a question during an October 22, 2008 conference call, defendant Termeer falsely assured investors that ***no*** issues had been raised in recent discussions with the FDA that might affect the approvability of the Lumizyme BLA, and that the "clinical data" – rather than any other concerns – "was the most important piece" for getting FDA approval. ¶¶103, 248-255.

Over the next four months, through the end of February 2009, Defendants continued to provide the market with further positive assurances that the Lumizyme BLA was on track, and that the Company was also positioned to meet growing demand for increased production of Cerezyme and Fabrazyme (whose production lines were all based at Allston). ¶¶257-58, 263-64, 266-71. In November 2008, Defendants did disclose that the FDA had extended the Lumizyme "PDUFA date" (i.e., the FDA's internal target date for issuing a decision on the Lumizyme BLA) from November 29, 2008 to February 28, 2009, on the grounds that it viewed certain aspects of the BLA as a "major amendment." ¶106. But this disclosure, like Defendants' other public statements during this period, continued to omit any mention of (a) Genzyme's (and Allston's) rampant compliance problems; (b) the viral outbreaks; (c) the October 2008 483; or (d) the fact (as discussed in the next section) that Genzyme's proposed plans to resolve the myriad deficiencies identified by that Form 483 had not been approved by the FDA, and (even if approved) did not even contemplate resolution of the problems at Allston until March 31, 2009 (*i.e.,* until at least a month *after* the February 2009 PDUFA date). ¶¶259, 262, 265, 272.

3. Investors Are Hit With News of the FDA's February 2009 Warning Letter, But Defendants Soften the Blow With New False Assurances

On February 27, 2009, Genzyme received a warning letter (addressed to Termeer) from the FDA regarding conditions at Allston (the "February 2009 Warning Letter"). It stated, in part:

> During the [Fall 2008] inspection the FDA investigators documented significant deviations from [CGMP] in the manufacture of licensed therapeutic drug products, bulk drug substances, and drug components. These products include Fabrazyme, Cerezyme and Myozyme. These deviations from CGMP include non-compliance with §501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the

> requirements of your [BLA] under §351 of the Public Health Service Act, and [21 C.F.R.] Parts 210 and 211.
>
> At the close of the inspection the investigators issued a form FDA 483, Inspectional Observations, which describe a number of significant objectionable conditions relating to your firm's compliance with CGMP....

¶113. It then reiterated the same serious observations contained in the October 2008 483. ¶115. Further, the Warning Letter also sharply criticized the (non-public) remedial plans that Genzyme had submitted (in response to the Form 483) to the FDA in late October 2008 for, *inter alia*:

- failing to address issues identified in the October 2008 483 regarding improper training;
- failing to explain what procedures Allston would develop for establishing the amount of microbiological contamination that could be detected on in-process material before remedial action would be taken;
- failing to explain how Allston would evaluate whether chemicals used in purification processes were properly formulated; and
- continuing to operate the fill line at excessive speeds.[6]

In other words, as the February 2009 Warning Letter confirmed, Genzyme's response to the October 2008 483 was *inadequate on its face,* largely because Defendants had simply promised to institute new procedures without ever specifying what those procedures might be. ¶101.

After the close of trading on March 2, 2009, Genzyme issued a release disclosing the existence of the Warning Letter and summarizing its contents. The release also noted that Genzyme had received a second letter (the "Complete Response Letter") from the FDA, which it described as "outlin[ing] the remaining items that had to be addressed before the [Lumizyme BLA] could be approved." ¶114. Defendants also acknowledged that, according to the FDA, Lumizyme would not be approved until the compliance problems had been resolved. ¶115.

Financial markets promptly reacted negatively to this news, as Genzyme shares fell on heavy trading by more than 7% on March 3, 2009, compared to the closing price the day before. ¶121.[7] As a J.P. Morgan financial analyst wrote on March 3:

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[6] This is only a partial list of the deficiencies that the FDA found with Genzyme's October 31, 2008 plan and timeline for addressing problems identified in the October 2008 483. For a fuller listing, *see* ¶101.

> *We [are] troubled at the lack of disclosure of the Form 483 issuance last fall, since we believe investors would have been more cautious on near-term Myozyme [Lumizyme] approval if it were clear that the FDA had formally cited the [Allston] facility for deficiencies as part of its standard review....* [Moreover,] [r]ather than making positive strides on resolution of these issues [raised by the October 2008 483], it is clear that the FDA was unsatisfied with the Genzyme response to the 483 since the agency escalated the issues to a Warning Letter. (¶120, emphasis added).

Yet Defendants' March 2 disclosures were only partial, and were combined with false and misleading assurances that continued to conceal the full truth. For example, on March 2, Defendants assured investors that (a) Genzyme had "readily at hand" all additional information requested by the FDA; (b) they were "confident that the products produced at the Allston facility continue to meet the ***highest*** quality and safety standards"; (c) "all corrective actions had either been completed or were on schedule to be completed by the original commitment date of March 31, 2009"; and (d) none of the deficiencies found by the FDA would adversely affect Genzyme's ability to continue to produce the drugs (*i.e.* Cerezyme, Fabrazyme and Myozyme-Lumizyme) made at Allston. ¶¶119, 275. At the same time, however, Defendants *continued* to conceal the unprecedented *two* viral outbreaks at Allston and Geel in September and November 2008, and *none* of their statements disclosed the extent to which the actual state of affairs at Allston risked exposing the Company (and its investors and customers) to further contamination problems and supply disruptions. Similarly, Defendants' assurances that all problems identified by the FDA were capable of being remedied within a matter of months, that Genzyme now had effective plans for doing so, and that its much-touted Lumizyme BLA (though delayed) was not at any serious risk of being rejected, were all patently false. ¶¶124, 276, 287A-D.

On March 11, 2009, *The Wall Street Journal* published excerpts of the actual text of the February 2009 Warning Letter, which it had obtained from the FDA. In response, Genzyme's stock price dropped another $2.37, or 4.3%. ¶129. However, the article also quoted defendant Bamforth as (falsely) reassuring investors that Genzyme "has addressed 80% of the problems

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[7] The negative reaction was likely greater than this 7% drop, as an earlier 4% drop in Genzyme shares on Friday, February 27, appeared to be caused by early leakage of news of the FDA warning letter. ¶122.

cited by the FDA and expects to resolve all of the issues by the end of April," and that the Allston plant "continues to produce treatments and the efficacy and safety of our products is unchanged."[8] ¶128. On March 24, 2009, Genzyme's Annual Report also reassured investors that Genzyme expected the Lumizyme BLA to be approved in mid-2009, and defendant Lawton similarly stated on April 22, 2009 that the Lumizyme BLA was "on schedule" for approval in the second or third quarter of 2009, that "***all*** of the corrective actions for Allston have been completed with the exception of one additional fill study that is unrelated to Lumizyme," and that "***at this point, we've actually resolved all of our outstanding issues with FDA***." ¶134 (emphasis added). These further statements were also materially false or misleading, as they continued to conceal the serious adverse facts discussed in the preceding paragraph. ¶¶128, 134.

Defendants' March and April 2009 disclosures were ***also*** materially false and misleading because – while continuing to discuss the pending Lumizyme BLA and the projected increased earnings that would begin to flow from Lumizyme once it was approved for sale in the U.S.[9] – they ***failed to disclose that Genzyme had recently made an internal decision to cancel its plans to manufacture Lumizyme for commercial sale in the U.S.*** Instead, Defendants had secretly decided to continue to seek FDA approval of 2000L Lumizyme ***solely*** to enable Genzyme to then file a supplemental BLA ("sBLA") for its 4000L product, which had recently begun production in Belgium but lacked required FDA approval for use in the U.S.[10] These undisclosed plans

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[8] The Individual Defendants claim that the *Wall Street Journal* article inaccurately quoted Bamforth, and that he had "actually" said only that Genzyme had created an action plan to address the problems and had completed 80% of that plan. (Indiv. Def. Br. at 28). Defendants apparently contend that the *WSJ* did not interview Bamforth directly, but instead misreported statements he made during a March 2 conference call. However, the *WSJ* article is plainly based on a separate interview with Bamforth, rather than the March 2 call, as the article attributes other statements to Bamforth that appear nowhere in the transcript of the March 2 call, including an account of an FDA meeting that did not occur until March 6. Folkman Decl. Ex. 2. In any event, the distinction between being "80% complete with Genzyme's plan to address deficiencies" and "80% complete in addressing deficiencies" would be a distinction without a difference.

[9] *See* ¶¶119, 275; *see also* ¶280 (defendant McDonough: "[our] comments here today reflect our ***commitment*** to bring [Lumizyme] approval to its natural conclusion here in the US to broaden access and fully satisfy the demand for Lumizyme.") (emphasis added).

[10] As Termeer conceded in December 2009: "We said [internally, in March 2009] we're no longer going to produce it, because we have a [European-]approved plant in Belgium that's dedicated and ... state-of-

would necessarily cause lengthy delays before any form of "mass-producible" (*i.e.,* 2000L or 4000L) Myozyme could be sold commercially in the U.S., because now Genzyme would have to await ***two*** new FDA approvals instead of one. ¶¶125-26, 287. Accordingly, the fraud continued.

4. Summer 2009: Allston Suffers Yet *Another* Viral Outbreak – And Defendants Continue to Mix Partial Disclosures With New False and Misleading Assurances

On May 21, 2009, Genzyme issued a release stating that it had submitted the final documentation addressing the FDA's outstanding issues regarding Lumizyme, that it had completed all other measures required to address the February 2009 Warning Letter regarding conditions at Allston, and that it still believed that Lumizyme would be approved in 2009. ¶138.

Less than a month later, on June 16, 2009, Genzyme announced that it had recently detected a viral contamination outbreak at Allston, and also disclosed – for the first time – the two earlier outbreaks of the same virus that had contaminated, and caused a decline in production at, Genzyme's Allston and Geel facilities just six and eight months earlier. In other words, although no other drug company had suffered a significant Vesivirus 2117 outbreak in 15 years, Genzyme was now experiencing its ***third*** such outbreak in less than nine months. ¶139. Genzyme also announced it would cease production at Allston for several weeks to thoroughly sanitize the plant, and that this would cause such significant supply constraints for Cerezyme and Fabrazyme that it would have to start rationing both of these highly profitable drugs, thereby materially reducing the Company's revenues and earnings for 2009. ¶¶140-41.[11]

In response to the belated disclosure of the two prior viral outbreaks and the third, ongoing outbreak at Allston, Genzyme shares fell almost $3, or 5.5%, on heavy trading. ¶145.

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the-art, and we must take – we must relieve the Allston plant.... So, it was a very artificial request to get approval for [Lumizyme] because that was a product that was no longer going to be produced." ¶126.

[11] To limit investor furor, and consistent with their stratagem of doling out adverse facts in drips and drabs, Defendants did ***not,*** however, disclose until later in June 2009 that the resulting severe Cerezyme and Fabrazyme shortages were a direct result of their decision months earlier to sell down the Company's Cerezyme and Fabrazyme inventories (while simultaneously reducing their production) in order to squeeze more Myozyme production out of the aging and already overburdened Allston plant. ¶140.

Yet once again Defendants' disclosures concerning actual conditions at Allston were incomplete, and contained renewed (and misleading) assurances that, aside from the latest viral outbreak, all was well. For example, on June 16, Defendants insisted that the recent outbreak had nothing to do with the compliance issues found by the FDA because, Defendants claimed, the FDA had signed off on conditions at Allston after its May 2009 inspection and agreed that the compliance issues there had been ***resolved.*** Defendant Lawton also reassured investors that the recent viral outbreak at Allston would neither require another inspection nor affect the Lumizyme BLA, and that Genzyme thus believed that the BLA was still on track for approval by November 2009, if not earlier. ¶143. But the assurances that the FDA's May 2009 inspection had resulted in a clean bill of health were simply untrue: to the contrary, as would later be revealed, the FDA concluded that Allston ***still*** suffered from numerous severe deficiencies that had not been rectified (and would demand a further re-inspection as a result). Nor was the latest contamination outbreak unrelated to Genzyme's compliance issues. Indeed, the FDA would soon (in November 2009) once again identify Genzyme's handling of raw materials (which Defendants had stated was the suspected cause of the outbreak (¶142)) as one of Allston's unremedied CGMP problems – ***and just two months later on August 14, 2009, defendants Termeer, Meeker, Lawton and Bamforth would send a private letter to the FDA concluding that both the recent contamination outbreak and ongoing compliance issues stemmed from a single set of "systemic causes" at Allston (as well as Framingham), and that they needed to make "fundamental systemic and cultural changes" at both plants***. ¶¶144, 170, 304-310.

On July 22, 2009, Genzyme issued a release belatedly disclosing what Defendants had secretly decided in March – namely, that (a) Genzyme would transition all Myozyme production to its 4000L Belgium facility to allow greater Cerezyme and Fabrazyme production at Allston, (b) it would no longer seek to manufacture Lumizyme (the 2000L version of Myozyme) for commercial sale, and (c) no "mass-producible" Myozyme (in the form of 4000L Myozyme from Belgium) would be available for sale in the U.S. until the second quarter of 2010 at the earliest

(after the pending 2000L BLA and as-yet-to-be-filed sBLA for 4000L product were approved), which was far later than Defendants' prior "no-later-than-November 2009" statements. ¶153. Genzyme also disclosed that, contrary to prior statements, it now expected a further FDA inspection of the Allston plant. ¶157. In response to these disclosures, on July 22 Genzyme's share price fell $4.70, or 8.4%, from the prior day's close.

However, these mid-June to July 22, 2009 statements continued to falsely assure investors by reiterating that all deficiencies that had been identified by the FDA had been, or soon would be, resolved, and that the Lumizyme BLA was on track for approval by November 2009. ¶¶147-61, 312-17. Accordingly, the fraud continued.

On July 31, 2009, Genzyme disclosed that it had received a letter from the FDA four days earlier stating that it *would* be reinspecting the Allston facility, and indicating that Defendants had *not* fully or adequately implemented previously promised remedial actions. In light of Genzyme's prior contrary representations, analysts were quick to identify these latest disclosures as "new surprises," and in response Genzyme shares fell $5.87 (or roughly 10.4%). ¶¶163-165. But Defendants' disclosures were still only partial, as they continued to conceal the full extent of the utter inadequacy of Genzyme's past remediation efforts or of the continuing compliance deficiencies at Allston (which, unbeknownst to investors, were actually so great that Defendants would *privately* describe them to the FDA a few weeks later as requiring *"fundamental systemic and cultural changes"*). ¶¶166, 170. Thus, the fraud continued.

From August to October 2009, Defendants continued to dribble out additional partial disclosures relating to the scope of the June 2009 viral outbreak at Allston, and the extent to which they had exposed Genzyme to increased risk of serious shortages of Fabrazyme and Cerezyme by previously drawing down inventories and reducing production. ¶¶169-77. However, even as late as October 21 and November 2, 2009, Defendants continued to falsely assure investors that they had taken thorough steps to address all compliance issues, and that Lumizyme would be approved by late November. ¶¶177, 318-20. Thus, the fraud continued.

E. November 2009: The Depth and Pervasiveness of Genzyme's Compliance Problems, and the Utter Inadequacy of Defendants' Touted Remediation Efforts, Are Finally Revealed

Despite their best efforts to assure investors that they had taken all steps needed to remedy all prior FDA concerns about CGMP compliance, by mid-November 2009 Defendants could no longer hide the fact that they had ***never even come close*** to getting their house in order.

On November 13, 2009 (the last day of the Class Period), Genzyme and the FDA issued a public notice disclosing that Genzyme had experienced yet ***another*** significant contamination episode at Allston – this time involving the discovery of foreign particles (including steel and non-latex rubber fragments as well as fiber-like materials from the manufacturing process) – in Cerezyme, Fabrazyme and Myozyme vials. The FDA warned that ingesting the particles could have serious adverse health effects, and also advised that its inspections at Allston remained ongoing. ¶¶178-81. This extraordinary revelation of *multiple* types of contamination in *multiple* products, and of continuing FDA inspections at Allston (which had started in early October) – especially after months of assurances that past problems had either been completely resolved or were (at worst) in the end stages of being resolved – was promptly and correctly interpreted by financial markets as proof that "Genzyme [was] not ready" for approval of the Lumizyme BLA, that its plans to use an approved Lumizyme BLA as a springboard for approval of an sBLA of 4000L Myozyme would therefore be still further delayed, and that problems at Allston were significantly more severe than Defendants had led the market to believe. ¶181.

Indeed, also on November 13, 2009, Defendants received both (1) a Second Complete Response Letter, which formally refused to approve Genzyme's pending Lumizyme BLA, and (2) another Form 483 for Allston (the "November 2009 483"). ¶183. The 22-page November 2009 483, addressed to defendant Termeer, listed a ***virtually unprecedented 49 separate types of significant CGMP violations*** observed during the FDA's recent inspections at Allston. These violations – far too numerous to list here – included: (i) lack of established operating procedures governing the frequency and contents of QA unit reviews; (ii) failure to properly handle raw

materials; (iii) failure to properly test for and investigate possible instances of microbial or particle contamination; (iv) failure to validate the sterilized fill process; (v) failure to train and qualify employees; (vi) failure to maintain multiple categories of records relating to sterilization of manufacturing equipment and testing for microbial or particle contamination of product; (vii) use of inadequate disinfectants; (viii) personnel flow and interaction that promoted contamination; (ix) failure to investigate instances of in-process material that tested outside expected ranges; and (x) failure to implement interim steps to address known metal particle contamination (*e.g.* rouging) problems caused by fill machinery before planned "long term" corrective actions were taken in 2010 and 2011. *See generally* ¶¶184-86.

In addition, the November 2009 483 contained numerous other observations showing how Genzyme had failed to adequately clean and decontaminate the Allston plant even after the second Vesivirus outbreak in June 2009. For example, the November 2009 483 cited Genzyme for (a) failing to ensure that the decontamination vapor reached all of the relevant areas; (b) failing to justify the placement of biological indicators used to test for the success of the decontamination; and (c) failing to follow up on locations where it was determined that decontamination had been ineffective. ***The November 2009 483 also flagged Genzyme for failing to implement the changes that it had promised after it received the October 2008 483, more than a year earlier.*** ¶185.

In response to the stunning disclosures of November 13, 2009 and the market's reaction to new contamination issues and their impact on the Lumizyme BLA, the price of Genzyme shares closed sharply lower, falling $3.89 (or roughly 7.3%) on unusually heavy volume. ¶188.

F. Post-Class Period Events

Events over the following weeks and months, *including statements from the Defendants' own lips*, only confirmed the extent to which Defendants had concealed information concerning the nature and extent of Genzyme's pervasive compliance problems throughout the Class Period.

1. Defendants' Admissions

On November 16, 2009, Genzyme held a conference call to discuss the November 2009 483 and the Second Complete Response Letter. During the call, defendant Termeer effectively admitted that the continuing compliance problems at Allston could be traced back to 2006, when Genzyme overburdened the plant by adding Myozyme on top of existing Cerezyme and Fabrazyme production lines. As Termeer conceded:

> We actually – ***the introduction of the production of Myozyme in Allston [in 2006] was a very significant factor in the complications we have experienced there***.... We can explain in a very clear way why and how it came that we overloaded the Allston facility with too much to do and then creating these difficulties. And the main reason, of course, was that we introduced Myozyme into [it]. ¶191.

During the call, Defendants also admitted that many serious problems identified in the just received November 2009 483 ***were the same ones that had plagued Genzyme for years, and that they had been fully aware of them***. Defendants, for example, admitted that many problems were traceable to Allston's reliance on outdated equipment. As defendant Meeker stated:

> [W]e do have a very specific issue at our Allston plant, which is related to the nature of the particulate matter, and that has to do with the age of the equipment. So specifically, the metal-on-metal contact, and that was, I think, part of what was highlighted in the FDA concern around the metallic particles...
>
> So ... the particulates are certainly part of it, but [the FDA is] looking at the fill/finish suite as a whole, and as I indicated earlier that is an older piece of equipment ***and so there was a number of issues that [the FDA] highlighted – many of which we were very aware of and were working to address, that we will continue to address....***
>
> [T]he other observations [pertaining to production rather than fill/finish] were mainly related ... to the documentation, for example, of different things that are performed in the plant, the training.... ***And these were elements that we obviously knew about, knew that we needed to continue to improve***. ¶192 (emphasis added).

See also ¶193 (Meeker: *"[M]uch* of what [the FDA] highlighted are things we understood and were working towards... I'm *not surprised* that there were some additional observations, [and] the fact that we needed to continue to work on fill/finish was ***not new***.") (emphasis added).

When an analyst asked why Genzyme had kept reassuring investors that issues had been resolved only to have the same problems keep "pop[ping] up again," defendant Meeker also

publicly admitted that the problems at Allston were symptomatic of quality problems across the Company, and represented systemic failures rather than isolated incidents. As Meeker stated:

> [W]e have employed a third-party consultant, the [Quantic] organization, who are specialists in the whole area of quality remediation, and it is with them that we have worked closely to develop this comprehensive plan... *And that has to do with every aspect of quality*, if you will, both in terms of revisiting the standards that we have, improving the overall – the corporate views of not just site specific, but these cut across the whole corporate operations function, the training that goes along with that, of course. ¶195 (emphasis added).

At a December 2009 biotech conference, Termeer similarly admitted that the problems at the overburdened Allston plant were due to both long-recognized problems with outdated equipment *and* deeply rooted systemic problems involving an "extremely familiar dynamic." As he stated:

> We put too much stress on the plant. We ran it 24 hours a day, ***over 100% capacity***.... [H]ow did we get here, what caused this stress, what caused the warning, the out of compliance situation? And this one has an angle to it, in addition to [the Allston plant's] old technology....
>
> ***[W]hen the plant gets into [a] position like this, when you run it as hard as we ran it, you get a certain dynamic that takes very significant effort to work out of the plant***. There is a human dynamic and we have people that are *extremely familiar* with that dynamic.... And so, to get that dynamic, get beyond it, that's what the FDA wants to see... ***But there is clearly a problem here.*** There are 500 people in the plant and they operate in a way that it's, ***to the outsiders, it seems like you should to be able to [fix it] just like that, but you can't.*** It is a dynamic to the plant that has to be worked very, very carefully ***and the culture in the plant, the discipline in the plant, all of that needs to be done***. ¶¶201-02 (emphasis added).

See also ¶170 (Defendants' non-public August 14, 2009 letter to FDA, conceding that FDA's past observations of CGMP violations were "only representative" of problems with "underlying systemic causes" that would require "fundamental systemic and cultural changes" to fix).

In December 2009 and January 2010, despite having repeatedly assured investors over the past 10 months that Allston's belatedly disclosed compliance issues had been (or soon would be) fully resolved, Genzyme announced that many key functions previously performed at Allston would be moved to its other facilities, *or outsourced entirely to other companies*. ¶¶203-04.

2. The $175 Million FDA Consent Decree

In the wake of the Genzyme debacle, the investment community openly criticized Termeer for his "arrogance" and called for his ouster, and excoriated Genzyme's "irresponsible

business culture." ¶215. Indeed, as *TheStreet.com's* Adam Feuerstein wrote after the Class Period: ***"Genzyme doesn't address and solve problems, instead it merely whitewashes over them, hoping that they either go away or can be disguised so well that no one notices."*** *Id.*

On May 24, 2010, the FDA made clear that it would have no more patience with the Defendants' history of incomplete, half-hearted and/or non-existent measures to remedy Genzyme's myriad, serious and systemic compliance problems. On that date, and in this Court, the government filed a complaint to permanently enjoin Genzyme and Termeer from committing further violations of the provisions of the Food, Drug and Cosmetics Act concerning the sale of adulterated drugs. Tellingly, the government's complaint (at ¶21) specifically alleged that it "believes that, unless restrained by this Court, Defendants will continue to violate the Act." [12]

In addition, also on May 24, 2010, defendant Termeer (individually and on behalf of Genzyme) entered into a ***consent decree*** with the government whereby Genzyme agreed:

- to pay an upfront civil penalty of ***$175 million*** (in the form of disgorgement of illegal profits derived from the sale of products from the non-compliant Allston plant);
- to transfer all fill/finish operations out of Allston for products sold within the U.S. by November 28, 2010 (and by August 31, 2011 for products sold outside the U.S.);
- to implement a comprehensive remediation plan under the oversight of an independent expert approved by the FDA;
- to pay substantial fines for failure to timely complete any of the steps contained in the remediation plan; and
- to submit to five additional years of oversight and annual outside reports, after full implementation of the remediation plan, by the FDA's approved outside experts (to be paid for by Genzyme).

[12] Copies of the government's "Complaint for Permanent Injunction" and the parties' "Consent Decree of Permanent Injunction" (filed under the caption *United States of America v. Genzyme Corp. et. al.,* No. 1:10-cv-10865) (D. Mass.), as well as a copy of Genzyme's May 24, 2010 press release, on Genzyme's Schedule 14-A filed with the SEC on May 25, 2010, concerning the same, are attached as Exhibits 1, 2 and 3, respectively, to the accompanying Declaration of Diane Zilka, dated August 5, 2010 ("Zilka Decl."). The Court can take judicial notice of court filings and SEC filings and, because they post-date the filing of the operative complaint, Plaintiffs request that the Court treat these materials as if they were incorporated into a supplemental pleading under F.R.C.P. 15(d).

Consent Decree (Zilka Decl. Ex. 2), at ¶¶8.A, 9, 6.C, 7 & 31. Further admitting how deeply rooted its compliance problems had always been, in a release that same day Genzyme stated that its new remediation plan would take "approximately ***2-3 years*** to complete." Zilka Decl. Ex. 3.

ARGUMENT

A. The Governing Legal Standards on a Motion to Dismiss

In deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a court must "accept[] all well-pleaded facts as [] true and draw[] all reasonable inferences in favor of" the plaintiff. *Fantini v. Salem State Coll.*, 557 F.3d 22, 26 (1st Cir. 2009). A complaint need only "contain factual allegations sufficient to 'raise a right to relief above the speculative level.'" *Morales-Tanon v. P.R. Elec. Power Auth.*, 524 F.3d 15, 18 (1st Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)); *see also Fantini*, 557 F.3d at 26 ("complaint must contain 'enough facts to raise a reasonable expectation that discovery will reveal evidence' supporting the claims") (quoting *Twombly*, 550 U.S. at 556).

The Private Securities Litigation Reform Act ("PSLRA") imposes heightened pleading requirements on §10(b) fraud claims, requiring §10(b) complaints to "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1). Plaintiffs must also "state with particularity facts giving rise to a strong inference" that defendants acted with scienter. *Id.* at §78u-4(b)(2). However, the PSLRA "do[es] not require a plaintiff to plead evidence." *In re Cabletron Sys., Inc.*, 311 F.3d 11, 33 (1st Cir. 2002); *Mississippi Pub. Employees' Ret. Sys. v. Boston Scientific*, 523 F.3d 75, 90 (1st Cir. 2008) ("'[I]n determining the adequacy of a complaint ... we cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence.'") (citation omitted).

B. Plaintiffs Plainly Allege Materially False and Misleading Statements and Omissions

To plead fraud in accord with the PSLRA, "a complaint [must provide] a clear and precise statement of what the alleged fraud consisted of ... supported by details that provide factual support for plaintiffs' allegations of fraud." *In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 198-99 (1st Cir. 2005). Plaintiffs need only allege facts that support a "reasonable belief" that defendants' statements were false. *Novak v. Kasaks,* 216 F.3d 300, 314 n.1 (2d Cir. 2000); *Cabletron*, 311 F.3d at 29 ("The approach we take, similar to *Novak*, is to look at all of the facts alleged to see if they provide an adequate basis for believing that the defendants' statements were false.") (internal quotes omitted); *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1099 (10th Cir. 2003) (allegations must support "reasonable belief" of falsity). A court's role is to "review the complaint only to determine that it pleads the existence of [misleading] statements and presents a plausible jury question of materiality." *In re PerkinElmer, Inc. Sec. Litig.*, 286 F. Supp. 2d 46, 52 (D. Mass. 2003) (quoting *Cabletron*, 311 F.3d at 34). "Information is material if a reasonable investor would have viewed it as 'having significantly altered the "total mix" of information made available.'" *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 44 n.10 (1st Cir. 2008) (quoting *Basic, Inc. v. Levinson*, 485 U.S. 224, 232 (1988)).

Although corporations may not have a general duty to promptly disclose all material information, "[w]hen a corporation does make a disclosure – whether it be voluntary or required – there is a duty to make it complete and accurate." *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 26 (1st Cir. 1987). When a company reveals "one fact about a product," it must then reveal other facts "that are needed so that what was revealed would not be 'so incomplete as to mislead.'" *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990) (en banc). A plaintiff need not demonstrate that there was an "independent duty to disclose" the omitted information in a vacuum; instead, "something may be material because of other information or explanations that

have been given by defendants." *Boston Sci.*, 523 F.3d at 87; *see also Baron v. Smith*, 285 F. Supp. 2d 96, 102 (D. Mass. 2003) ("context is important" when evaluating materiality).

Here, the Complaint alleges that Defendants repeatedly failed to tell investors critical facts about Genzyme's gross departures from CGMP, and their impact on the Lumizyme BLA and other aspects of the Company's business, while later mixing incomplete partial disclosures with fraudulent assurances. As a result of these omissions, Defendants' public statements, which fall into the following four general (and somewhat overlapping) categories, were rendered false and misleading:

1) ***Statements Concerning the Status of Genzyme's Application for FDA Approval of Lumizyme and Genzyme's Manufacturing Operations:*** Defendants repeatedly told investors that Lumizyme was on track for early FDA approval, when Defendants knew that undisclosed compliance problems seriously jeopardized the chances for approval [*e.g.*, ¶¶217, 230, 235, 246, 255, 270, 275-76, 297, 316, 318-19];

2) ***Statements Concerning the February 2009 Warning Letter:*** After publication of the Warning Letter belatedly disclosed the existence of numerous problems at Allston, Defendants continued to mislead investors by falsely assuring them that the problems were capable of quick resolution, or had already been resolved, when in fact (as the Company would later admit) the problems were "systemic" and not remotely capable of being quickly or easily resolved. [*e.g.*, ¶¶275, 278-279, 289, 294, 299, 302, 308, 312, 314, 316];

3) ***Statements Concerning Genzyme's Plans With Respect to the Manufacture and Marketing of Lumizyme:*** Although Genzyme had secretly decided in March 2009 to abandon its plans to manufacture and market Lumizyme commercially in the U.S., Defendants continued to assure investors that Lumizyme was on track for imminent approval for commercial production in the U.S., and to issue financial projections that depended on Lumizyme sales that were no longer planned [*e.g.*, ¶¶280, 283, 290, 292, 299, 305, 308, 312, 314]; and

4) ***Statements relating to Cerezyme and Fabrazyme and the Company's Growth:*** Defendants repeatedly told investors that Genzyme had built solid foundations for growth, that its markets for Cerezyme and Fabrazyme were expanding, and that (after the disclosure of the February 2009 Warning Letter and the June 2009 contamination outbreaks) its ability to supply these two drugs would be unaffected. To the contrary, both Cerezyme and Fabrazyme production were adversely affected by the rampant CGMP violations, and by Genzyme's earlier (but undisclosed) decision to cut back production of both drugs due to overburdening at Allston. [*e.g.*, ¶¶218-19, 223-225, 234, 237-38, 240, 249, 251, 257, 263, 266, 268, 282, 284, 292-293, 297].

1. Misleading Statements Regarding the Status of the Lumizyme Approval Process and Genzyme's Manufacturing Operations

Beginning in October 2007, Termeer and Meeker told investors that FDA approval of Lumizyme was "expected" by the first quarter of 2008. ¶217. After the FDA requested that the Lumizyme application be submitted as a new BLA rather than a supplemental BLA and assigned a November 2008 PDUFA date, Defendants then repeatedly told investors that they were on track to commercialize Lumizyme (i.e., both to receive FDA approval and to make the drug available for commercial sale) by early 2009. ¶¶230, 235, 246. As the Company also reported in its 2007 10-K, "[a]ll facilities and manufacturing techniques used for the manufacture of Genzyme's products must comply with applicable FDA regulations governing the production of pharmaceutical products known as 'Good Manufacturing Practices.'" ¶226.

Defendants made similar statements even after Genzyme had experienced the two undisclosed viral contaminations in the fall of 2008 and received the October 2008 483 following the FDA's mandatory pre-approval inspection at Allston. For example, when directly asked on an October 22, 2008 conference call whether an FDA committee had any concerns about manufacturing relating to the Lumizyme BLA, defendant Lawton stated only that there was "really just a discussion about the biochemical differences that we know exist between the 160 and the 2000-liter scale," and that the clinical data was the "most important piece" (¶255) – and over the next several months Defendants reassured investors that Lumizyme "continue[s] to be on track" for approval in 2009. ¶270. Defendants also attributed production delays and costs to "incomplete process validation runs" at its new Geel facility, which defendant McDonough falsely claimed were "part of the normal development process that we would undergo for a new facility" – rather than disclosing that they were the result of a Vesivirus 2117 outbreak. ¶¶109, 266, 271, 291.

However, as previously summarized in the statement of facts above, these statements were false and misleading because they failed to disclose, *inter alia:*

- That the Allston facility was plagued with pervasive CGMP violations that permeated every aspect of manufacturing (¶¶55-82), including the misuse of basic equipment and failure to (a) conduct fundamental tests to ensure it was functioning correctly, ¶¶61, 65-66, 69-70, 79, (b) employ basic anti-contamination and sterile procedures, ¶¶60, 62, 66, 68, (c) hire qualified employees or conduct basic training, ¶¶77-78, mishandling of raw materials used in production, ¶¶75-76, or (d) employ basic procedures for quality assurance and documentation, ¶¶67, 72-74, 81;

- That the problems (as Defendants would later admit privately to the FDA) were the result of "underlying systemic causes" necessitating "fundamental systemic and cultural change" in Genzyme's manufacturing facilities, ¶170, and could also be traced to deliberate decisions from as early as 2005 to overload the aging Allston facility. ¶¶54-56, 148, 191-92, 194.

- That the FDA, in its required pre-approval inspection in September and October 2008, had identified many of these CGMP violations, ¶¶98-99;

- That Defendants' plan to address the problems identified by the FDA ignored numerous FDA observations and explicitly envisioned that at least some proposed corrective measures that were proposed would not be completed by the dates by which Genzyme represented that Lumizyme would be approved, ¶¶100-02, and that Defendants failed to implement the measures that their own remedial plans had called for, ¶162;

- That Genzyme had experienced at least two highly-unusual viral contamination outbreaks in the last year as a result of itse failures to adhere to CGMP, ¶¶95-97, 104;

- That the production delays at Geel were actually due to a rare viral contamination, and were not part of the "normal development process" for a new plant. As defendant McDonough admitted in June 2009 after a third viral contamination forced Allston to shut down, Defendants had actually known of the severity of the Geel contamination and had taken extraordinary measures to cleanse that plant, ¶272(B); and

- Far from being diversified, Genzyme had forced production of virtually all of its most profitable and important drugs into the Allston plant which, as described above, was obsolete and being run far beyond its capacity. ¶¶148, 173, 175, 191, 201.

These problems were so pervasive that the FDA later issued a public health warning regarding products manufactured at Allston, and Genzyme was ultimately forced to move much of its manufacturing operations out of this plant. ¶¶180, 198, 204. And after the FDA issued a second and more detailed Form 483 at the end of the Class Period on November 13, 2009 – the basis for the FDA's Complaint and Consent Decree – Defendants admitted that the compliance problems identified were the same ones that had existed back in October 2008. ¶¶183-87, 191-95, 201-02.

Genzyme continued to mislead investors even after it disclosed the FDA's February 2009 Warning Letter and its receipt of the October 2008 483. For example, as Termeer told investors in March: "we are confident we will be able to resolve all remaining issues with the FDA within three to six months," and that "we have a very high level of confidence indeed that we will get through this approval and will be able to start to make product available to all patients" within six months ¶¶117, 275-76.[13] As Lawton similarly told investors on May 6, 2009, "we are very confident in [that] we've been working really closely with the FDA, and they have clearly been working with us. They've said all along that they're going to work to expedite this approval, so I think we are confident that they are not going to take that full six months, and that approval will be earlier." ¶297.[14] Genzyme also stated that "[w]e believe that the products produced at [Allston] continue to meet the highest quality and safety standards," and that notwithstanding the FDA's criticism, "the efficacy and safety of our products is unchanged." ¶¶275, 289.

These statements were false and misleading for the reasons given above, and because Genzyme's deficiencies were not capable of being remedied in a matter of just a few months (and thus approval of the Lumizyme BLA would be further delayed). For example:

- Contrary to Defendants' claims that they were "working closely" with the FDA, the Company continued to fail to address the issues the FDA had raised, ¶¶162, 183-187;
- As Defendants would later privately admit to the FDA in their August 14, 2009 letter, the problems at Allston (and the Framingham "hub" for raw materials) were "systemic," and the FDA's observations of serious CGMP violations were in fact only "representative" of the systemic departures from CGMP that permeated Genzyme's manufacturing operations, ¶170;
- These CGMP violations threatened the safety of Genzyme's products to the point where Allston soon suffered another viral contamination outbreak, followed by an FDA public health advisory warning of metal particulates stemming from Allston's use of obsolete equipment, ¶180; and

[13] *See also* ¶290 ("We anticipate" Lumizyme approval "in mid-2009"); ¶294 (Genzyme is "on schedule" for submission of remaining information to the FDA "with approval in late Q2 [2009] and or sometime in Q3") ¶312; ¶316; ¶318. The Complaint's reference to "mid-2000" is a typographical error.

[14] *See also* ¶299 (Genzyme's 1st Q 2009 10-Q, issued May 8, 2009, representing that "given our ongoing dialogue with the FDA, we believe that we could receive approval before the PDUFA date").

- The problems at Allston were so pervasive that the Company decided in March 2009 that it could not manufacture Lumizyme there for commercial sale in the U.S. – a decision that was concealed until July 2009, ¶¶125-26, 153, 199.

In mid-June 2009, Allston experienced another viral outbreak so severe that the plant had to be shut down for decontamination. Upon announcing the news, the Company finally admitted the existence of the prior viral outbreaks. However, Genzyme *continued* to insist that the FDA was "mov[ing] ahead" with approving Lumizyme, and that the recent contamination outbreak would not require a further inspection and would not affect the timetable for approval of the Lumizyme BLA. ¶¶143, 305, 308, 312-13. Defendants bolstered these assurances (as discussed further below) by Genzyme's insistence that the FDA had determined in May that Allston was now compliant with CGMP, that the viral contamination was unrelated either to the previous CGMP deficiencies or to the Lumizyme application, and that the Warning Letter was unrelated to the Lumizyme BLA, ¶¶304-08, 312-13. Genzyme also told investors that the Company was expecting Lumizyme approval in November 2009 right up until November 2, 2009, just before the end of the Class Period. ¶¶316, 318-19.

These statements were false and misleading for the reasons stated above, including:

- The Allston facility was *still* not in compliance with CGMP. For example (and as the FDA's May 2009 inspection only confirmed), Defendants had failed to implement remedial measures that they had promised to put in place – such as failure to validate the cryoshippers that Genzyme used to transfer raw materials (i.e., the likely source of the prior multiple Vesivirus outbreaks at Allston), ¶162; and

- Defendants had failed even to institute appropriate decontamination procedures in the wake of the viral contamination. Among other things, Defendants had failed to ensure that the decontamination vapors reached all relevant areas, and had failed to follow-up in locations where it had found that decontamination was not effective. ¶185.

As a result, the FDA later refused to approve the Lumizyme BLA on November 13, 2009, and simultaneously issued a public health warning for Allston products, as well as another Form 483 listing Allston's compliance problems in even more detail. ¶¶180, 183. Thereafter, Defendants

would publicly admit that the compliance problems identified in November 2009 were the same as those that had existed back in October 2008. ¶¶183-87, 191-95, 201-02.

In the face of the Complaint's detailed allegations of undisclosed compliance deficiencies, Genzyme primarily contends (Br. at 20-24) that, as a *matter of law*, companies are *never* required to disclose receipt of a Form 483, or the existence of compliance problems. Genzyme grossly mischaracterizes its duties under the federal securities laws.

a. Genzyme's Failure to Disclose Severe and Pervasive CGMP Violations Rendered Their Positive Statements Materially Misleading

As noted above, the information that a company must disclose depends on context. *Baron*, 285 F. Supp. 2d at 103. Accordingly, even if there is no general duty to reveal manufacturing problems in all circumstances, defendants must disclose information if "omission of the information creates a materially false impression of the company's well-being." *Id.*; *see also Gross v. Summa Four, Inc.*, 93 F.3d 987, 992 (1st Cir. 1996) (a duty "may arise if, *inter alia*, a corporation has previously made a statement of material fact that is either false, inaccurate, incomplete, or misleading in light of the undisclosed information."). Thus, the relevant question is *not* whether Genzyme had a freestanding "duty to disclose" manufacturing difficulties or the October 2008 483, but whether Defendants' failure to disclose the nature and extent of its underlying compliance problems rendered their positive statements materially misleading. As the First Circuit has stated, "[S]omething may be material because of other information or explanations that have been given by defendants. *Thus plaintiff does not need to rely on a theory that there was an independent duty to disclose the manufacturing change.*" *Boston Sci.*, 523 F.3d at 87 (emphasis added); *see also In re PerkinElmer,* 286 F. Supp. 2d at 53 (court must examine "(1) whether the defendants' statements … could be found to be material, that is, having significance to a reasonable investor, and (2) whether the plaintiffs have adequately alleged that the statements were false or misleadingly incomplete").

Courts routinely find that when a corporation publicly predicts FDA approval of a new product, the failure to disclose regulatory problems that threaten approval renders its statements misleading. In *In re Able Labs.*, 2008 WL 1967509 (D.N.J. March 24, 2008), the court held that public predictions of FDA approval of new products were false and misleading due to undisclosed deviations from CGMP, as evidenced by a warning letter, the accounts of confidential witnesses, and a Form 483 issued at the end of the class period. *See id.* at *14-15. Similarly, in *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005), the court found that after defendants received, but did not disclose, a Form 483 identifying "significant objectionable conditions" in their manufacturing, it was misleading for them to predict FDA approval and to tout the progress of the clinical side of their application. *See id.* at 1121-22, 1129-30. And in *In re Sepracor, Inc., Sec. Litig.*, 308 F. Supp. 2d 20 (D. Mass. 2004), the court refused to dismiss the complaint where defendants claimed they were "confident" that their drug would be approved by the FDA, but plaintiffs alleged that defendants were aware that their submissions did not meet all FDA requirements. *See id.* at 31-34.[15]

Although Genzyme (Br. 23-24) cites various cases for the proposition that it had no duty to disclose manufacturing problems, in those cases plaintiffs did not allege the existence of *any* misleading statements. For example, in *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Mat'ls, Inc.*, 2010 WL 889864 (E.D. Mo. Mar. 8, 2010), plaintiffs alleged only that defendants

[15] *See also Warshaw v. Xoma Corp.*, 74 F.3d 955, 959 (9th Cir. 1996) (§10(b) violated when drug company did not "adequately qualif[y] its optimism" about the possibility of FDA approval, given its knowledge of defects in its application); *McGuire v. Dendreon*, 2008 WL 5130042, at *5 (W.D. Wash. Dec. 5, 2008) (misleading to tell investors that company had "hosted a good inspection" when it had resulted in a Form 483); *In re Connetics Corp. Sec. Litig.*, 2008 WL 3842938 (N.D. Cal. Aug. 14, 2008) (misleading to project approval of new drug and to characterize conversations with FDA as favorable while failing to disclose FDA's safety concerns); *In re CV Therapeutics, Inc.*, 2004 WL 1753251, at *7-8 (N.D. Cal. Aug. 5, 2004) (misleading to project drug approval while failing to disclose FDA's safety concerns); *In re Pozen Sec. Litig.*, 386 F. Supp. 2d 641, 645-46 (M.D.N.C. 2005) (misleading to portray results of clinical studies in a positive light while concealing facts showing that drug application did not meet FDA requirements); *In re NPS Pharms., Inc.*, 2007 WL 1976589 (D. Utah July 3, 2007) (same); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983 (S.D. Cal. 2005) (same); *In re Transkaryotic Therapies, Inc. Secs. Litig.*, 319 F. Supp. 2d 152, 161 (D. Mass. 2004) ("failure to disclose FDA's serious criticism [of a new drug application] is a material omission" particularly in light of overall context of defendants' statements and importance of the timing of approval).

should have revealed certain manufacturing problems as they experienced them, instead of waiting a month to discuss the problems in a quarterly SEC filing (*id.* at *2), but did not allege that defendants made *any* statements between the time the problems occurred and the time they revealed them to the public. *See id.* at *4-5. Thus, far from holding that there is some blanket rule that relieves companies of a duty to disclose manufacturing problems, the court simply reached the unremarkable conclusion that, *under those facts*, the plaintiffs had failed to allege an untrue statement of material fact (or omission of a fact "necessary in order to make the statements made ... not misleading") in violation of Rule 10b-5.[16]

The same analysis holds when a drug company receives a Form 483 or other unfavorable FDA communication. The question is *not* whether there exists a general duty to disclose the communication, but whether the *failure* to disclose such information renders the defendants' statements misleading. "A company seeking FDA approval of a new drug clearly is not under any obligation to disclose every single issue raised by the FDA throughout the process. *However, if the FDA expresses significant concerns regarding the sufficiency [of an aspect of the application], the company cannot make affirmative representations regarding the completeness or sufficiency of [that aspect] without full disclosure.*" *In re Amylin Pharms., Inc. Sec. Litig.*, 2003 WL 21500525, at *8 (S.D. Cal. May 1, 2003) (emphasis added).

Anderson v. Abbott Labs., 140 F. Supp. 2d 894 (N.D. Ill. 2001), cited by Genzyme, is not to the contrary. There, the court concluded that none of the defendants' statements had been rendered misleading by the alleged omissions, *see id.* at 904-05, 908-09, a conclusion based partly on an examination of the affirmative statements issued by the defendants (*id.*), and partly on an examination of the nature of the undisclosed facts (*id.* at 902). In particular, the court

[16] Genzyme's other citations are similarly distinguishable. *See In re Ford Motor Co. Sec. Litig.*, 184 F. Supp. 2d 626, 632-33 (E.D. Mich. 2001) (public statements were truthful and not contradicted by omitted information); *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 459-60 (S.D.N.Y. 2000) (after full discovery, plaintiffs were unable to identify any materially misleading statements that would have triggered a duty to disclose internal problems); *In re Union Carbide Class Action Sec. Litig.*, 648 F. Supp. 1322, 1327 (S.D.N.Y. 1984) (finding the omissions immaterial only after "examin[ing] the relationship" between the omissions "and the affirmative statement allegedly made misleading").

noted that the undisclosed FDA warning letter had been "boilerplate," and that viewed in the context of the company's regulatory history the letter did not have any particular significance – and that the company's stock price *did not move* in reaction to the letter's eventual disclosure. *Id.*; *see also No. 84 Employer-Teamster Jt. Council Pension Tr. Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 935 (9th Cir. 2003) (whether there is stock price drop is a factor to consider in evaluating materiality). The court did not purport to advocate (let alone create) a bright-line rule relieving companies of all duties to disclose manufacturing problems; to the contrary, the court held that the capacity of an omission to materially mislead investors rests on a continuum that depends on the overall context." Consequently, materiality is more like a continuum than a simple yes or no, material or immaterial." *Anderson*, 140 F. Supp. 2d at 903.

Defendants' reliance on the readily distinguishable *Acito v. IMCERA Group, Inc.*, 47 F.3d 47 (2d. Cir. 1995) is also misplaced. There, the Second Circuit did not purport to hold that an FDA report of manufacturing deficiencies is immaterial as a matter of law; instead, it held only that the reports *in that case* were immaterial because they concerned one small manufacturing site of minimal importance to a global company, and because, based on the FDA reports the defendants had received, they reasonably believed that the situation was dramatically improving. *Id.* at 52-53. Similarly, in *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142 (D. Mass. 2007), *rev'd on other grounds*, 523 F.3d 75 (1st Cir. 2008), the district court dismissed a claim based on the failure to disclose certain FDA warning letters because (1) the only arguably misleading statements identified by plaintiffs were puffery (and thus the omitted information did not render any statements misleading); (2) as in *Acito*, the FDA letters concerned only a *minor* portion of the company's overall manufacturing facilities; and (3) there was ultimately ***no*** enforcement action taken.[17] *See id.* at 161-62.[18]

[17] Although the plaintiffs in *Boston Scientific* did not appeal this aspect of the court's ruling, in reversing a different aspect of the court's decision, the First Circuit emphasized that "something may be material because of other information or explanations that have been given by defendants." 523 F.3d at 87. Thus, to the extent that the district court appeared to examine the "materiality" of the warning letters independently of the allegedly false statements, such analysis has been rejected by the First Circuit.

Here, by contrast, Defendants eventually admitted that Genzyme's CGMP compliance problems were "not new," had existed for years, were "systemic," and were not capable of being remedied in a matter of mere weeks or months. ¶¶170-71, 193, 201-02; *see also* Zilka Decl. Ex. 2. Unlike the situation in *Acito*, far from having been told by the FDA that the plant was effectively addressing its compliance problems, Defendants' *own plan* did not propose to remedy the problems by the date(s) that Defendants said Lumizyme would likely be approved, ¶100. Their plan also left several issues entirely unremedied, and twice during the Class Period the FDA faulted Genzyme for failing to address the FDA's concerns or to implement even those partial (and inadequate) measures that Genzyme said it would adopt. ¶¶101, 162. Finally, in further sharp contrast to *Boston Scientific*, Genzyme's CGMP problems were anything but minor, as evidenced by the FDA's escalating enforcement actions, the abandonment of the Lumizyme BLA, Defendants' decision to move many of its operations out of Allston entirely, and, perhaps most tellingly, Defendants' own *private* admissions to the FDA in August 2009 that Genzyme's problems were "fundamental" and "systemic." Thus, these problems were plainly ***highly*** material to investors. *See McGuire v. Dendreon*, 2008 WL 5130042, at *6 n.4 (W.D. Wash. Dec. 5, 2008) (contents of Form 483 "would significantly alter the total mix of information available to the reasonable investor because it bears on potential delays in the approval of Dendreon's only near-commercial status product"); *Yanek*, 388 F. Supp. 2d at 1129 (Form 483 related to "facts bearing on possible delays in FDA approval of the ICL," and such facts were "material because STAAR's entire strategy depended on the timely approval and commercial launch of the ICL"). Indeed, as one analyst wrote after Genzyme finally disclosed the months-old October 2008 483 in March 2009: "[W]e remain troubled at the lack of

[18] This is exactly the reasoning of the court in *In re Apollo Group Sec. Litig.*, 395 F. Supp. 2d 906 (D. Ariz. 2005). There, the defendants failed to disclose a report by the Department of Education that criticized their incentive policies at a university that accounted for the majority of their revenues. *See id.* at 907. The court distinguished *Acito* and *Abbott Labs* on the ground that, unlike in those cases, the undisclosed DOE report was of great significance to the company, and therefore "at the point Defendants chose to speak about the DOE investigation, they had a duty to speak fully and truthfully and such full disclosure would have included the negative DOE Report." *Id.* at 920.

disclosure of the Form 483 issuance last fall, since we believe investors would have been more cautious on near-term Myozyme approval if it were clear that the FDA had formally cited the facility for deficiencies as part of its standard review." ¶120.

Nor is it relevant that a Form 483 is not a "final FDA determination." Genzyme Br. 20. Under the PSLRA, Plaintiffs are required to allege "facts that show exactly why the statements or omissions were misleading." *Stone & Webster*, 414 F.3d at 194. Here, Plaintiffs allege that Allston was grossly out of compliance with CGMP throughout the Class Period, and base their allegations in part on FDA inspection reports. Such reports plainly provide sufficient "clarity and basis" to allege that the problems existed during the Class Period, and thus these facts must be taken as true. *See* Fed. R. Evid. 803(8) (hearsay exception for public records involving "matters observed pursuant to duty imposed by law as to which matters there was a duty to report"); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (complaint's factual allegations must be accepted as true); *Able Labs.*, 2008 WL 1967509, at *16 (accepting contents of Form 483 as true for pleading purposes); *In re Cryolife, Inc.*, 2003 WL 24015055, at *8 (N.D. Ga. May 27, 2003) (same). Even *In re Discovery Labs. Sec. Litig.*, 2007 WL 789432, *3-4 (E.D. Pa. Mar. 15, 2007), cited by Genzyme, accepted for pleading purposes that the deviations from CGMP identified in a Form 483 actually existed, and were material to investors.

Plaintiffs have ***also*** alleged additional facts to show that severe compliance issues existed at Allston, including: (1) Defendants' own admissions that they knew of the problems at Allston throughout the Class Period, that they were "systemic" and the product of a "culture of noncompliance," and that Genzyme had overburdened the aging and outdated Allston plant, ¶¶170-71, 191-94, 201-02; (2) the FDA's February 2009 Warning Letter, July 2009 letter and November 2009 483, and its repeated rejections of the Lumizyme BLA, ¶¶112-113, 162, 183-87; (3) Defendants' decision to abandon the Lumizyme BLA and to pull several major production operations out of Allston, ¶¶198-199, 204; (4) the accounts of numerous confidential witnesses

who worked at Allston and Framingham, and who stand essentially unchallenged,[19] ¶¶63, 66, 76, 78, 82, 102; and (5) most recently, the $175 million Consent Decree and the appointment of an outside monitor. Thus, the Complaint "sets forth a clear and precise statement of what the alleged fraud consisted of" and "is not the kind of vague prelude to a fishing expedition that Congress sought to bar" by enacting the PSLRA. *Stone & Webster*, 414 F.3d at 198.[20]

Genzyme is equally wrong to argue that because a Form 483 is not a "final" FDA decision, its existence is immaterial to investors as a matter of law. Form 483s can only be issued for "significant objectionable conditions" observed by an FDA inspector. For this reason, some courts have held that a Form 483 is actually *per se material* to investors. *See, e.g.*, *Dendreon*, 2008 WL 5130042, at *5. Moreover, the October 2008 Form 483 was issued in the context of a pending new drug application that was critical to Genzyme's growth, and concerned the facility that produced Genzyme's three most important products (90% of its Myozyme production for most of the Class Period, and *all* of its Cerezyme and Fabrazyme), rendering it quite significant to investors. That a Form 483 may not represent a final determination – or that the problems may still be remediable by the Company – does not make its existence immaterial.

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[19] That some confidential witnesses worked at Allston *prior to* the Class Period is of no moment, as "evidence of past practice may indeed be probative of present practice." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 202 (1st Cir. 1999); *see also Able Labs.*, 2008 WL 1967509 at *2 ("[B]oth post-class-period data and pre-class-period data [can] be used to confirm what a defendant should have known during the class period, since any information that sheds light on whether class period statements were false or materially misleading is relevant.") (quoting *In re Merck & Co. Sec. Litig.*, 432 F.3d 261, 271-72 (3d Cir. 2005) (alterations omitted).

[20] Genzyme relies heavily on *Public Pension Fund Grp. v. KV Pharma. Co.*, 2010 WL 681443 (E.D. Mo. Feb. 22, 2010). There, the defendant company repeatedly represented that it complied with CGMP despite having received several undisclosed Form 483s. Ultimately, the company was forced to suspend its operations, recall all of its products, and the FDA opened a criminal investigation that resulted in a consent decree. The court nonetheless found that plaintiffs had not pled the existence of regulatory violations with sufficient particularity because the Forms 483 did not represent final FDA determinations. *Id.* at *10. *KV Pharma,* however, goes against the great weight of authority, and by refusing to accept FDA inspection reports as a sufficient basis for alleging the existence of regulatory violations, the court apparently imposed a higher pleading standard than even that imposed by the Federal Rules of Evidence. *See* Fed. R. Evid. 803(8). In this Circuit, plaintiffs are not required to plead evidence to satisfy the PSLRA, and courts are encouraged to consider a case's pre-discovery posture when evaluating the sufficiency of a complaint. *Boston Sci.*, 523 F.3d at 90; *Cabletron*, 311 F.3d 33. In any event, Plaintiffs here do not rely exclusively on the October 2008 483 to establish the existence of regulatory violations.

As the First Circuit has stated, "Present, known information that strongly implies an important future outcome is not immune from mandatory disclosure merely because it does not foreordain any particular outcome." *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1210 (1st Cir. 1996).[21]

Finally, relying on *KV Pharmaceutical*, Genzyme contends that because the October 2008 483 was available to the public via a Freedom of Information Act ("FOIA") request, it should be considered "public" information and therefore cannot form the basis of a securities fraud claim. Genzyme Br. 22. Courts have recognized that if truthful information is conveyed publicly, it may offset or counterbalance a defendant's false statements. *See Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000). However, the defendant must demonstrate that the truthful information was "conveyed to the public 'with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information created by' the alleged misstatements" – a factual inquiry that is almost never appropriate for determination on a motion to dismiss. *Id.* (quoting *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir.1989)); *cf. Stone & Webster*, 414 F.3d at 208 (court must inquire whether the publicly-disclosed truthful information rendered the false information immaterial "as a matter of law"). Here, although the October 2008 483 might have been available to a person who made the effort of filing a FOIA request, there has been no showing that anyone did so during the Class Period, let alone that the information in the October 2008 483 was distributed to the public "with a degree of intensity and credibility sufficient to counter-balance" Genzyme's misstatements. Therefore, the October 2008 483 was not "public" and could not offset Genzyme's false statements. Indeed, Genzyme's position is absurd; it would place upon all investors the continuing burden to regularly submit

[21] Nor is Genzyme (Br. at 24) correct to argue that the Complaint is really about "poor management." Although Genzyme's conduct may have constituted mismanagement, §10(b) encompasses claims alleging that defendants "were aware that 'mismanagement had occurred and made a material public statement about the state of corporate affairs inconsistent with the existence of the mismanagement,'" exactly as alleged here. *Serabian v. Amoskeag Bank Shares, Inc.*, 24 F.3d 357, 361 (1st Cir. 1994) (quoting *Hayes v. Gross*, 982 F.2d 104, 106 (3d Cir. 1992)); *see also In re Donna Karan Int'l Inc. Sec. Litig.*, 1998 WL 637547, *10 (S.D.N.Y. Aug. 14, 1998) ("[T]he mere fact that the conduct in question arguably constitutes mismanagement will not preclude a claim under the federal securities laws if the defendant made a statement of material fact wholly inconsistent with known existing mismanagement").

FOIA requests regarding all pharmaceutical companies because of the hypothetical possibility that one company may have received a Form 483 without disclosing it.[22]

b. Genzyme's Statements Were Rendered Misleading by the Failure to Disclose the Viral Contaminations

Defendants also assert they were under no obligation to disclose the existence of the two viral contaminations prior to the June 2009 shut-down.[23] Despite Genzyme's factual argument to the contrary, Plaintiffs adequately allege that the viral contaminations were directly linked to Genzyme's rampant deviations from CGMP. For example, in Defendants' private letter to the FDA in August 2009, they conceded that the "viral investigation" at Allston must proceed "in the context of the broader compliance remediation activities," and that as part of its efforts to remedy the CGMP violations, Genzyme would have to "focus[] on prevention of viral contaminations in the future." ¶170. Moreover, though Genzyme (Br. at 30) offers the factual assertion that the problems identified in the October 2008 483 only concerned the "fill and finish" operations rather than the bioreactors where the viral contamination occurred, this is not true: indeed, the

[22] There is no assurance that any such investor would even receive the Form 483 in a timely fashion. In this case, Plaintiffs only obtained the October 2008 483 after a six-week delay following their FOIA request; even then, the copy was redacted. See Zilka Decl. ¶5. These factual issues are precisely why a truth-on-the-market defense cannot be decided on the pleadings. *See, e.g., In re Amgen, Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1025 (C.D. Cal. 2008) (refusing to conclude, on motion to dismiss, that a notice in the Federal Register was sufficiently conveyed to the public to offset defendants' false statements). In the analogous context of determining whether an investor's claim is time-barred because "public" information put the investor on inquiry notice, courts refuse to rule as a matter of law that a reasonable investor will consult all publicly available records "of which the investor might later, for some purposes, be charged with constructive knowledge." *Corwin v. Marney Orton Inv.*, 843 F.2d 194, 198 (5th Cir. 1988); *see also Staehr v. Hartford Fin. Servs. Group*, 547 F.3d 406, 418 (2d Cir. 2008) (investors not deemed on notice of complaint filed in California because "the only way this lawsuit could have come to the attention of the investing public was if someone had encountered it while examining the docket of the Superior Court of San Francisco County"); *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 238-39 (S.D.N.Y. 2006) (analogizing truth-on-the-market inquiry to inquiry notice).

[23] To the extent Defendants' argument is premised on their own factual assertions, it must be rejected. For example, the Court cannot accept Defendants' unsworn testimony that they were unaware that the production slowdowns were due to viral contamination and that it was "investigating" the cause for the nine-month period between September 2008 and June 2009 (Genzyme Br. 12). Moreover, Genzyme ultimately admitted that it was aware that the very first contamination in September 2008 was serious enough to warrant a major investigation and decontamination efforts, and that the Company suspected a virus from the very beginning. ¶272(B). By the time the same problem resurfaced in November 2008, forcing the Company to draw down existing inventory, ¶173, Genzyme certainly was able to discern that its CGMP violations were having a concrete effect on its ability to continue manufacturing.

October 2008 483 criticized Defendants' handling of cryoshippers, in which raw materials were shipped from the Framingham raw materials "hub" to Allston and Geel, as well as numerous other deficiencies in Genzyme's anti-microbial contamination practices. Defendants themselves admitted that the virus likely contaminated their plants through the raw materials, ¶¶142, 157, 167, and the Framingham facility, by Defendants' own admission, also suffered from "systemic" compliance issues, ¶¶170-71. Thus, a connection is plainly alleged between Genzyme's deviations from CGMP and the viral contaminations that forced Allston to shut down in June 2009.[24] The October 2008 483 also identified serious documentation problems specifically with respect to the manufacture of drug substances, and with respect to monitoring of "deviations" from proper procedures. McLaughlin Ex. A at 1-2, 5. These problems would have also seriously interfered with Defendants' ability to identify, remediate and prevent contamination.

Defendants' *own submissions* to this Court further demonstrate that the CGMP violations and the viral contaminations were almost certainly intertwined. In support of their motions to dismiss, Defendants submitted a copy of the Complete Response Letter they received on February 27, 2009, informing them that the FDA would not approve Lumizyme. Plaintiffs had never before seen this letter: although its existence was publicly announced, the text was not disclosed and was not provided in response to Plaintiffs' FOIA request. Zilka Decl. ¶5. The letter states that "Cell viability is a critical parameter for controlling product quality during fermentation. *You will need to provide adequate justification for not using cell viability as an inprocess control for bioreactor monitoring.*" McLaughlin Dec. Ex. F (emphasis added). The viral contamination at issue attacks cell viability – the very area that Defendants did *not* monitor. Had they had proper controls, they would have detected the virus more quickly and mitigated its effects. At the least, this FDA finding undercuts Defendants' attempt to disassociate the

[24] Additionally, the November Form 483 listed a number of violations in the production area as well as fill/finish. Defendants characterized the November Form 483 as identifying basically the same problems that were identified in the October 2008 483, ¶192, and Defendant Meeker admitted that the Company was "***not surprised***" by observations concerning production. ¶193.

contaminations from the CGMP violations as a basis for dismissal, and highlights the degree to which formal discovery should provide even further support for Plaintiffs' claims.

Indeed, as a matter of common sense, Genzyme's argument is simply implausible. Genzyme would have this Court believe that Allston – with its massive deviations from CGMP, including violations of numerous procedures designed to ensure sterility and prevent contamination, ¶¶57-82 – by the purest coincidence "just happened" to experience two extraordinarily-unusual viral contaminations in the space of seven months. Such a far-fetched inference should not be drawn in Defendants' favor – particularly on a motion to dismiss – when the more reasonable conclusion, at the pleading stage, is that the viral contaminations were a direct, if not *inevitable*, result of Defendants' failure to follow proper procedures.

To the extent that Genzyme contends that its disclosures of a production delay and "tight" Myozyme supplies were sufficient to inform the market of the problems, this factual "truth on the market" issue is inappropriate for resolution on a motion to dismiss, as discussed above, and is facially meritless. Genzyme falsely attributed the September 2008 Geel contamination to the ordinary costs of starting up a new plant even though McDonough later *admitted* that Defendants knew that the Geel problems were far more extensive, requiring extraordinary decontamination efforts. ¶272(B). And Defendants did not disclose the November 2008 contamination at Allston until it was finally forced to shut Allston down entirely in June 2009; thus, investors were entirely unaware that the problems were due to a recurring virus, let alone that they were ultimately attributable to Genzyme's own lack of compliance with CGMP.

In sum, because the viral contaminations cannot be divorced from the other manufacturing problems that Genzyme was experiencing, the failure to disclose them rendered Genzyme's statements false and misleading.

2. Misleading Statements Regarding Measures Taken to Remedy Compliance Problems Identified in the February 2009 Warning Letter

After Genzyme disclosed the February 2009 Warning Letter and the October 2008 483, Defendants spent the rest of the Class Period reassuring investors that they could easily resolve the issues identified by the FDA. For example, they immediately told investors that the issues raised by the FDA only concerned "documentation," that the Company had such information "readily at hand," ¶¶275, 279; *see also* ¶278, that the Company had "addressed 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April," ¶289 (*see also* ¶294), and that as a result, the Company did not expect to be reinspected. ¶281.[25] By the end of April, the Company was telling investors that "at this point we've actually resolved all of any outstanding items with FDA," ¶294, and "[w]e believe that we have addressed all the measures required to respond to the FDA warning letter," ¶299 – assurances that continued through July 2009. ¶¶302, 308, 312, 314, 316. After the Company ended up hosting the very reinspection that it had earlier assured investors would not be necessary, Genzyme insisted that the "inspection actually closed out with the inspector informing us that we had indeed satisfactorily addressed all of the items in the warning letter for Allston," and once again assured investors that the items in the Warning Letter had been addressed and that a new inspection after the June viral contamination would not be necessary. ¶¶304, 305, 307, 312, 314.

These statements were false and misleading because:

- As the FDA later concluded, Genzyme did not implement the corrective procedures it had promised to undertake, ¶¶162, 192;
- The problems at Allston were pervasive and fundamental, and went far beyond mere "documentation," ¶¶57-82. As Defendants later admitted, the problems had never been resolved, and Defendants were aware throughout the Class Period that "systemic" noncompliance at Allston was caused by a "culture" of noncompliance, ¶¶170-71, 191-94, 201-02; and

[25] The Company also told investors that it did not believe there would be a reinspection because when the Company had received a previous Warning Letter in connection with its Lyon facility, there had been no reinspection. ¶118. Later, the Company admitted that there *had* been a reinspection at Lyon. ¶132.

- The problems were so pervasive that Defendants determined in March 2009 that they would not be able to manufacture Lumizyme at Allston; ultimately the Company was forced to move major manufacturing operations out of Allston entirely, and entered into a consent decree with the FDA after a public health warning was issued for products manufactured at Allston, ¶¶180, 198, 199, 204.

Courts routinely hold that issuers may be liable under §10(b) when they falsely represent the status of their compliance with regulations and their discussions with regulatory agencies. *See Cryolife,* 2003 WL 24015055, at *9 (securities fraud properly alleged where company falsely represented that it had implemented remedial measures requested by FDA and CDC); *In re CV Therapeutics, Inc.*, 2004 WL 1753251, at *7-9 (N.D. Cal. Aug. 5, 2004) (statements were misleading when they downplayed the depth of the FDA's concern and minimized the amount of work that would be necessary to allay those concerns); *Transkaryotic Therapie*, 319 F. Supp. 2d 152, 159-61 (D. Mass. 2004) (same); *In re Apollo Group Sec. Litig.*, 395 F. Supp. 2d 906, 919-20 (D. Ariz. 2005) (securities fraud claim properly pled where defendants falsely portrayed status of an ongoing regulatory investigation); *Am. W.*, 320 F.3d at 928-29 (securities fraud properly pled where company misdescribed the impact and nature of regulator's concerns). Here, just as in those cases, the Complaint properly alleges that not only was Allston out of compliance with CGMP throughout the Class Period, but it also never satisfied the FDA's concerns at any point, despite Defendants' representations to the contrary. Thus, Plaintiffs have properly alleged the element of falsity.

3. Misleading Statements After Receipt of the February 2009 Warning Letter Regarding Alleged Plans to Market Lumizyme Commercially

Even after Genzyme abandoned plans to commercially manufacture Lumizyme in March 2009, Defendants falsely – and repeatedly – told investors that "we're keeping Lumizyme for the adult population," ¶280; that following FDA approval, the product "will be marketed as Lumizyme in the United States," ¶283; that Genzyme had made a "commitment to bring this near-final phase of the 2000 liter approval to its natural conclusion here in the US to broaden access and fully satisfy the demand for Lumizyme, in this case for US Pompe patients," ¶280; and that the Company intended to quickly commercialize Lumizyme as soon as FDA approval

was received, ¶314; *see also* ¶290. Defendants also misleadingly emphasized that they were continuing to pursue FDA approval of Lumizyme, and continued to project future revenues that included commercial sales of Lumizyme, ¶¶292, 299, 305, 308, 312, while omitting the critical fact that Lumizyme would never be sold in the United States, ¶¶125-26, 129. Through these statements, Defendants falsely represented their manufacturing capabilities, their intentions for the drug, and the future revenues it represented. *See Cabletron*, 311 F.3d at 36 (company had "duty to revise" false impression left by its statements "if later developments substantially undermined the accuracy of the earlier statements").[26]

Genzyme does not even deny that these statements were false and misleading. Instead, it attacks them solely on "immateriality" and loss causation grounds – two equally baseless arguments that are separately addressed at §E.2 and §F below.

4. Additional False and Misleading Statements

Both before and after the Company experienced the first two viral contaminations and received the October 2008 483, Genzyme boasted of the success of its Genetic Diseases Segment. Investors were told of the rapid growth in sales for Cerezyme and Fabrazyme, which the Company attributed to "new patient accruals" and "continued identification" of new patients. ¶¶218, 225, 234, 238, 240, 249, 251, 257, 268, 284, 293. The Company also boasted of Myozyme's rapid growth, calling it the "fastest growth rate that we've seen in any of our

[26] Genzyme argues (Br. at 49, n.45) that because Termeer only admitted that Genzyme changed its plans in March without specifying the exact date, this court must assume that the decision was made on March 31, and that any statements regarding Lumizyme prior to that date were truthful. To the contrary, drawing inferences in Plaintiffs' favor, it is reasonable to infer that Genzyme internally decided to abandon commercial production of Lumizyme during the three-day delay between the date it received the FDA's Warning Letter and the date it was disclosed to the public. This is especially so because, as Termeer himself stated, the decision to abandon Lumizyme was based in part on Genzyme's recognition that, following European approval of the Geel plant in Belgium, the Company could supply the European market solely with product made in Belgium. ¶199. The Geel plant received European approval on February 26, ¶111, just in time to influence Genzyme's response to the Warning Letter, which Genzyme received the next day, ¶112. In any event, even if the decision was reached later in March, Genzyme continued to tell investors over the next several months that it expected imminent approval of the Lumizyme BLA, and to declare its intention to market the drug commercially, while omitting the crucial fact that it knew that Lumizyme would never be sold. ¶¶290, 292, 299, 305, 308, 312, 314.

lysosomal storage diseases or any product for that matter." ¶238; *see also* ¶¶224, 228, 233, 237-38. The Company emphasized that the "growth potential" for the LSD segment "remains strong," projecting "robust growth" with associated revenues, ¶¶223, 224, 237, 263, 266, 268, 293, 297. Investors were encouraged to view the present results through the lens of what they portended for the future: as Termeer put it in October 2008 – after the Company had received the October 2008 483 – the Company had had "an extremely productive quarter in terms of building for the future." ¶249. Investors were also told that "we don't expect there to be, given the very long-term extremely solid experience that we have around Cerezyme to be any particular reason for patients to shift or to change" to competing medications. ¶219. And even after the FDA issued the February 2009 Warning Letter, Genzyme told investors that "we don't anticipate that these observations will have any impact on our supply," ¶282, and Termeer assured investors that "we are managing the company in a very conservative way," and "not taking for granted that everything will happen the way that we wish it to happen." ¶292.

These statements of the Company's then-existing state of its operations and potential for revenues and growth were all materially false and misleading because:

- Genzyme did not have the manufacturing capacity to meet the growing demand for Cerezyme and Fabrazyme of which it boasted; for years, it had been using its capacity at Allston to manufacture Lumizyme, while selling down its inventories of Cerezyme and Fabrazyme, ¶¶148, 173,191, 201. As Termeer later admitted, "The reason we were short of capacity was that we didn't keep up entirely with the capacity needs of the company to keep the inventories," ¶175;

- The "growth" in demand for Cerezyme and Fabrazyme had only been achieved through gross deviations from CGMP and overburdening at Allston, which required that the plant be run 24 hours a day, beyond its capacity, for years, ¶¶57-82, 201;

- By November 2008, the Company had experienced two instances of a highly unusual viral contamination that slowed production even further, ¶¶95-96, 104-05; and

- Genzyme's abandonment of CGMP, the stress placed on the Allston facility, the decision to sell down inventories of Cerezyme and Fabrazyme, and the undisclosed viral contaminations and Form 483 did not represent conservative management and did not create a platform for future growth; instead, these factors drastically increased the risks of interruptions in the supply of product, thus threatening revenues and endangering the popularity of both Cerezyme and Fabrazyme with patients, ¶¶83-87.

"[I]f [a defendant] puts the topic of the cause of its financial success at issue, then it is 'obligated to disclose information concerning the source of its success, since reasonable investors would find that such information would significantly alter the mix of available information.'" *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 240 (S.D.N.Y. 2006) (quoting *In re Van der Moolen Holding N.V. Sec. Litig.*, 405 F. Supp. 2d 388, 400-01 (S.D.N.Y. 2005)); *see also Sloman v. Presstek, Inc.*, 2007 WL 2740047, at *5 (D.N.H. Sept. 18, 2007); *In re Providian Fin. Corp. Sec. Litig.*, 152 F. Supp. 2d 814, 824-25 (E.D. Pa. 2001); *In re EVCI Colls. Holding Corp. Sec. Litig.*, 469 F. Supp. 2d 88, 101-02 (S.D.N.Y. 2006). Similarly, it is misleading to offer optimistic predictions while tying those statements to false characterizations of present or past facts. *See, e.g.*, *In re Nortel Networks Corp. Sec. Litig.*, 238 F. Supp. 2d 613, 628 (S.D.N.Y. 2003) ("Linking future success to present and past performance does not render statements immune from liability."); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1021 (S.D. Cal. 2005) ("All investing is based to some degree on investors' perceptions about the future;" fraud exists where "Defendants' misstatements of fact formed a false basis" for investors' perceptions of the future of the company); *Am. W.*, 320 F.3d at 928, 933 n.11 (misleading to report positive financial results that were only made possible by refusing to incur costs necessary to comply with regulatory requirements).

Here, Genzyme explicitly attributed its growth to "patient accruals" and "new markets," while omitting critical facts showing that such "expansion" was achieved at the expense of CGMP and depletion of the Company's inventories of Cerezyme and Fabrazyme. At the same time, Genzyme encouraged investors to consider these results when gauging the likely future performance of the Company. Therefore, these statements also misled investors.

C. The Complaint Adequately Alleges Scienter

The PSLRA requires that a complaint identify facts giving rise to a "strong inference" of scienter. 15 U.S.C. §78u-4(b)(2). An inference is considered "strong" if it is "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551

U.S. at 324. A court's job is "not to scrutinize each allegation in isolation but to assess all the allegations holistically," and to determine whether the averments, "accepted as true and taken collectively, would [allow] a reasonable person [to] deem the inference of scienter at least as strong as any opposing inference." *Id.* at 326; *see also Biogen IDEC*, 537 F.3d at 45 ("Scienter must be examined by looking at the complaint as a whole.").[27] The inference of scienter "need not be irrefutable, i.e., of the 'smoking gun' genre, *or even the 'most plausible of competing inferences*,'" but need only be "at least as compelling" as any plausible opposing inference. *Tellabs*, 551 U.S. at 324 (emphasis added). Accordingly, "where there are equally strong inferences for and against scienter, *Tellabs* now awards the draw to the plaintiff." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 59 (1st Cir. 2008). In the context of a corporate defendant like Genzyme, "[t]he scienter alleged against the company's agents is enough to plead scienter for the company." *Cabletron*, 311 F.3d at 40.

Scienter may be pled by demonstrating either the defendants' knowledge of falsity, or by showing that defendants acted with either a conscious intent to defraud or a high degree of recklessness. *Boston Sci.,* 523 F.3d at 85. The First Circuit has identified several factors that are indicative of scienter, including "the fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete," *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002), "disregard of the most current factual information before making statements … and the self-interested motivation of defendants in the form of saving their salaries or jobs." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 196 (1st Cir. 1999). Plaintiffs need not allege direct evidence of scienter; indirect evidence will suffice to raise the requisite strong inference. *Cabletron*, 311 F.3d at 38.

[27] The court's obligation to weigh competing inferences does not alter the long-standing rule that the allegations of the Complaint must be accepted as true, with all reasonable inferences drawn in favor of Plaintiffs. *See Tellabs*, 551 U.S. at 326; *ACA Fin.*, 512 F.3d at 58; *Boston Sci.*, 523 F.3d at 85.

1. Plaintiffs' Allegations Give Rise To A Compelling Inference Of Defendants' Scienter

Plaintiffs' allegations include admissions by Defendants themselves of their knowledge of undisclosed facts that rendered their statements false and misleading. Additionally, Plaintiffs have alleged circumstantial evidence that strongly supports an inference of Defendants' scienter, including the pervasiveness of the CGMP problems and their centrality to the Company's core business function. These allegations, coupled with Defendants' motive and opportunity to commit fraud, give rise to a cogent and compelling inference of their scienter.

a. Defendants' Own Admissions and Communications with the FDA Evidence Their Knowledge Of Facts Contrary To Their Statements

Both during and after the Class Period, Defendants admitted their knowledge of critical facts that they failed to disclose, or that contradicted their Class Period statements. For example:

- Defendants admitted at the end of the Class Period that the October 2008 483, the Warning Letter, and the November 2009 483 all described the same basic deficiencies which "***we were very aware of*** and were working to address" and were "***elements that we obviously knew about, knew that we needed to continue to improve***" and involved "things that we understood and were working towards" ¶¶8, 88, 192, 193 (emphasis added). Meeker even went so far as to say that he was "***not surprised***" by the contents of the November 2009 483 and its list of 49 separate deficiencies. ¶193.

- In an undisclosed August 2009 letter to the FDA, Defendants Termeer, Meeker, Lawton, and Bamforth all privately acknowledged that "the ***FDA's observations are only representative***" and that there were "underlying systemic causes" for the deficiencies at both Allston and Framingham, necessitating "***fundamental systemic and cultural changes to our operations***." ¶170 (emphasis added).

- Termeer admitted in November 2009 that Defendants knew that Allston relied on obsolete and aging equipment, but that Genzyme had nonetheless "overloaded the Allston facility with too much to do," putting "too much stress in the plant" and running it "24 hours a day, ***over 100% capacity***." ¶¶191, 194, 201.

- After the Class Period, Termeer admitted that Defendants' March 2009 decision to cancel plans to manufacture Lumizyme for commercial sale in the U.S. was due to the seriousness of the compliance issues at Allston, combined with the lack of capacity to safely and simultaneously produce reasonable quantities of Lumizyme, Cerezyme, and Fabrazyme at the same plant ¶199. Thus, Defendants knew as early as March that (1) Allston was so far out of compliance that it could not handle the manufacture of Lumizyme; and (2) Lumizyme would never be sold commercially in the U.S.

- Defendants admitted in June 2009 that supply constraints of Fabrazyme and Cerezyme were due to Genzyme's undisclosed Class Period decision to reduce their

production (while simultaneously selling down inventories of these drugs) in order to squeeze more Myozyme production out of Allston ¶¶140, 148. That decision – which endangered Genzyme's product pipeline as well as the lucrative "orphan" drug designation attributed to Fabrazyme and Cerezyme ¶¶83-87 – was inconsistent with Defendants' public statements about growth in demand for Cerezyme and Fabrazyme.

These admissions of *contemporaneous knowledge* of facts contrary to their public statements or that rendered their statements misleading support a strong inference of scienter. *See Boston Sci.*, 523 F.3d at 87 (knowingly omitting material information is probative of scienter); *Shaw*, 82 F.3d at 1224 (scienter sufficiently alleged when plaintiffs provided "a series of factual allegations relating to a combination of developments known to the company...that could have provided a basis for advance knowledge" of information contrary to their public statements); *Simon v. Am. Power Conversion Corp.*, 945 F. Supp. 416, 434 (D.R.I. 1996) (scienter supported by statements that reasonably could be read as admissions that company knew that defects in its products would hurt revenues).

Defendants' communications with the FDA also alerted them to the severity of the Company's CGMP problems:

- Termeer received the October 2008 483 and the February 2009 Warning Letter (¶¶98, 112), and each of the other Individual Defendants was a corporate-level officer of Genzyme who either saw or was aware of the contents of these documents (¶¶330, 334), both of which detailed serious CGMP violations at Allston.

- Defendants' *own plan* for remedying the deficiencies in the October 2008 483 (1) envisioned that certain remedial measures would not be complete until *after* the date by which Defendants were publicly predicting Lumizyme's approval, (2) ignored entirely certain concerns raised by the FDA, and (3) provided inconsistent responses to other deficiencies identified. ¶¶100-101.

- According to the FDA Complaint filed in connection with the Consent Decree, FDA investigators discussed the violations listed in the October 2008 483 and the Warning Letter with Genzyme's management. FDA Complaint ¶¶18-20.[28] Nonetheless, the investigators continued to observe CGMP violations at subsequent inspections, FDA

[28] The Court may consider the FDA Complaint when evaluating the inference of scienter. *See In re Brooks Automation, Inc. Sec. Litig.*, 2007 WL 4754051, *10 (D. Mass. Nov. 6, 2007) (considering allegations in SEC complaint when evaluating scienter, as "[i]t is well-accepted that federal courts may take judicial notice of proceedings in other courts if those proceedings have relevance to the matters at hand.") (quoting *Kowalski v. Gagne*, 914 F.2d 299, 305-06 (1st Cir. 1990)).

Complaint ¶17, thus prompting the FDA to reprimand Defendants for failing even to implement the measures they had promised to undertake. *Id.* ¶¶18, 21.[29]

- The FDA Complaint described the February 2009 Warning Letter as emphasizing serious CGMP deficiencies, and stated that the issues were discussed with Genzyme's management at a March 6, 2009 meeting. FDA Complaint ¶19 (Zilka Decl. Ex. 1).

- During analyst conference calls, Defendants represented that they had personal knowledge of the ongoing discussions with the FDA regarding the compliance issues and the Lumizyme application, reassuring investors that they were "working really closely" with the FDA on these matters, ¶¶135, 252, 282.

Despite these facts, before it received the February 2009 Warning Letter, Defendants continued to publicly predict Lumizyme's near-term approval without even hinting at the existence of any problems – indeed, Defendants denied that there were any manufacturing issues that would present a stumbling block to approval. *See* ¶¶103, 106, 108, 216-217, 220, 230, 235, 239, 240, 246, 249-250, 252-253, 255, 258-59, 261, 269-271. And after receiving that Warning Letter, Defendants reassured investors that the problems mainly concerned "documentation," and had either already been resolved or would be fixed in a matter of weeks. ¶¶275, 278-279.

In *Boston Scientific*, the First Circuit found that scienter was adequately pled where the complaint alleged that the maker of defective medical devices knew of negative reports from doctors about the product and had instituted manufacturing changes to correct the defect, but publicly attributed the problems to doctors' unfamiliarity with the product instead of any product defect. 523 F.3d at 90-91. Similarly, here Defendants knew of serious, unremedied CGMP violations at Allston, and knew those problems would affect the Lumizyme BLA and production of both Cerezyme and Fabrazyme, but falsely downplayed those problems and stated that all had been fixed (or promptly would be). Defendants' failure to disclose the true extent and severity of their deficiencies supports a strong inference of scienter. *See also In re Connetics Corp. Sec.*

[29] One confidential witness reported that, in response to FDA criticisms about a lack of proper training in October 2008, Genzyme simply told employees at Allston to ask for additional training if they needed it. ¶102. Another employee at Framingham described Genzyme's training procedures in exactly the same way. ¶82. Genzyme has not challenged either of these accounts, but even if it had, the First Circuit has held that consistent, corroborating accounts of witnesses strengthen each other and provide an adequate basis from which to infer both falsity and scienter. *Cabletron*, 311 F.3d at 29-30.

Litig., 2008 WL 3842938 at, *8, *11 (N.D. Cal. Aug. 14, 2008) (scienter inferred from defendants' failure to disclose FDA's "serious concerns" about new drug application); *Transkaryotic Therapies*, 319 F. Supp. 2d at 152, 162 (D. Mass. 2004) (same); *CV Therapeutics*, 2004 WL 1753251, at *10 (same); *Serabian v. Amoskeag*, 24 F.3d 357, 368 (1st Cir. 1994) (scienter adequately alleged where complaint cited "reports and documents presented to defendants at relevant times that were inconsistent with defendants' public statements").

This case is distinguishable from *Boston Sci.*, 490 F. Supp. 2d 142, which Defendants cite for the proposition that mere receipt of a Form 483 or an FDA warning letter does not equate to knowledge of CGMP non-compliance or that the FDA would take enforcement action. (Indiv. Def. Br. at 10-11). Unlike the warning letter in *Boston Scientific,* which the court found was unrelated to any enforcement report and resulted in no adverse action against the company, here the reverse is true: the October 2008 483 was just the *beginning* of a series of increasingly pointed warnings from the FDA (including the February 2009 Warning Letter and November 2009 483) that Genzyme faced severe consequences for its continuing lack of compliance, culminating in a Consent Decree and $175 million fine to resolve a FDA injunction action.

Instead, the case at bar is analogous to *Mallozzi v. Zoll Med. Corp*, 1996 WL 392146 (D. Mass. Mar. 5, 1996), where this Court found that the complaint alleged scienter because the defendants sought to portray the company (a manufacturer of cardiac resuscitation products regulated by the FDA) as having no regulatory compliance problems when the company (a) had been receiving an escalating series of communications from the FDA that increasingly criticized the company's operations; (b) had violated FDA regulations and the terms of FDA warning letters; and (c) had to recall many more machines than the defendants had disclosed. Similarly, in *Yanek v. Staar Surgical Co.*, the court found that an inference of scienter was sufficiently supported by allegations that, at the time the defendants made forward-looking statements about FDA approval of a new product, the company was actually experiencing FDA compliance problems, as reflected in a Form 483 and subsequent warning letter, and that the defendants

knew the problems could preclude FDA approval of the new product. 388 F. Supp. 2d at 1131-32. *See also Dendreon*, 2008 WL 5130042, at *7-8 (because a Form 483 is material, the concealment from investors of its existence is probative of deliberate recklessness, as was defendants' choice to not disclose the existence of the 483 while characterizing the FDA's facility review process as a "good inspection").

Here, too, the Complaint alleges Defendants' awareness of severe and undisclosed compliance problems at Allston, at the same time they were making positive statements about the likelihood of FDA approval of Lumizyme and continued strong revenues from the core drugs produced at Allston. Plaintiffs also allege how Genzyme's pervasive compliance problems were totally concealed until March 2009, and how Defendants' subsequent statements (while noting the existence of *some* problems), repeatedly failed to disclose that the problems were "systemic" and "fundamental" – and instead further assured investors that all (or virtually all) compliance deficiencies had been addressed. Such allegations support a *compelling* inference of scienter.[30]

Defendants contend that they accurately reported the nature of their discussions with the FDA. The FDA, however, has characterized its February 2009 Warning Letter as describing serious deficiencies (FDA Complaint ¶¶19-20), whereas Defendants told investors the problems were remediable within weeks and pertained mainly to documentation. ¶¶275, 278-79. Defendants provide no factual basis for an inference that they were merely reporting what the FDA told them when they assured investors in April and May 2009 that they had solved all of the CGMP deficiencies identified in the Warning Letter ¶¶134, 137. To the contrary, given that the Allston plant's deficiencies resulted in a consent decree, a public health warning, and a transfer of major manufacturing operations out of the facility within a year after Defendants

[30] Defendants contend that no inference of scienter can be drawn because communications from the FDA regarding CGMP deficiencies were not "final" determinations (Indiv. Def. Br. 10). However, as the cases cited above illustrate, companies cannot simply ignore rebukes from their chief regulatory agency. *See Able Labs.*, 2008 WL 1967509, at *16 (scienter inferred from defendants' failure to respond to issues identified in a Form 483); *Cryolife*, 2003 WL 24015055, at *12-13 (scienter inferred from defendants' failure to respond to FDA communications, including warning letters and Forms 483).

claimed to have received a clean bill of health – and given that FDA inspectors are actually *forbidden* from communicating a proposed or planned regulatory action before its official issuance[31] – the inference that FDA inspectors told Genzyme that it was in compliance with CGMP and that Lumizyme would be approved by its PDUFA date is highly implausible.

b. The "Core Operations" Doctrine Supports Scienter

The fraud in this case relates to conditions at Genzyme's flagship facility ¶54, which produced Genzyme's key revenue-producing products, and which collectively accounted for nearly 50% of Genzyme's total product revenue in 2008. ¶¶36-39, 41, 263. The fraud also concerned Myozyme and its 2000L Lumizyme variant, Genzyme's most-watched and most important new product – indeed, as one financial analyst put it, "at the end of the day, what moves the needle of growth for Genzyme is Myozyme [Lumizyme]." ¶52.

When a company's key business segment or product is the subject of misleading statements, courts routinely hold that executives are likely to have been aware of the true facts, thereby strengthening (if not supporting independently) the inference of scienter. *See Aldridge*, 284 F.3d at 84 (scienter inferred from fact that relevant product line "was very important" to the company and a "primary driver" of growth). Similarly, as the Seventh Circuit held (on remand from the Supreme Court) in *Makor Issues & Rights Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 707-09 (7th Cir. 2008), where misrepresentations and omissions concern a company's "most important products," they are much more likely to result from an intent to deceive or recklessness on the part of management. As the court reasoned: "That no member of the company's senior management who was involved in authorizing or making public statements about the demand for the [core product] knew that they were false is very hard to credit . . ." *Id.* at 709.[32]

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[31] *See* Guidance for Review Staff and Industry - Good Review Management Principles and Practices for PDUFA Products (page 8), April 2005 Procedures, U.S. Dep't of Health and Human Services, FDA Centers for Drug Evaluation and Research (CDER) and for Biologics Evaluation and Research (CBER)

[32] *See also Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 988 n.5 (9th Cir. 2008) ("[t]he size of the contract and the prominence of the client raise a strong inference that defendants would be aware of this order"); *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 424-425 (5th Cir. 2001) (inferring corporate officers' scienter where fraud involved company's core product); *In re RAIT Fin. Trust Sec. Litig.*, 2008 WL

The Individual Defendants, as members of Genzyme's senior management, had direct oversight of and actively managed its manufacturing practices, its quality controls, its drug application processes, and its regulatory affairs. ¶¶25-33, 331, 333.[33] Critically, FDA regulations ***charged*** the Individual Defendants, as members of senior management, with the responsibility of ensuring compliance with CGMP at Allston. ¶¶8, 44, 324, 331; *see also* FDA Compl. at ¶5 (Zilka Decl. Ex. 1). The Individual Defendants' roles and responsibilities, coupled with the centrality of Allston and the Lumizyme BLA to Genzyme's business, strongly support an inference of their scienter. *See Boston Sci.*, 523 F.3d at 91 ("It is fair to infer the company has highly effective information systems. Defendants are in a highly regulated industry [manufacturing medical devices] and the company, it can be inferred, constantly monitors reports of patient injury . . . ."); *PerkinElmer*, 286 F. Supp. 2d at 54-55 (scienter inferred in part because the defendants "held positions that would have given them not only access to, but close familiarity with, the details of [the company's] affairs").[34]

5378164 at *13 (E.D. Pa. Dec. 22, 2008) ("Because the alleged misstatements involved RAIT's core business operations and because the Officer Defendants had ample reason to know of the falsity of their statements, there is a strong inference of scienter in this case."); *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 19 (D. Mass. 2004) (inferring knowledge on part of company's top executives "given the importance of the [product's] sale to Ionics' business that year").

[33] Termeer and Wygza signed Sarbanes-Oxley ("SOX") certifications, which report on management's evaluation of internal controls and disclaim any knowledge of fraud, among other things. *See* ¶¶225, 234, 240, 257, 283, 298, 319. Contrary to the Individual Defendants' argument, this fact supports an inference of Termeer's and Wyzga's scienter. *See In re ProQuest Sec. Litig.*, 527 F. Supp. 2d 728, 743 (E.D. Mich. 2007) ("The SOX certifications give rise to an inference of [ ] scienter because they provide evidence either that he knew about the improper accounting practices or, alternatively, knew that the controls he attested to were inadequate"); *In re Lattice Semiconductor Corp. Sec. Litig.*, 2006 WL 538756 at *17-18 (D. Or. Jan. 3, 2006) (signing of SOX certifications supports strong inference of scienter; the certification requirements "were expressly intended to prevent top executives from using a 'head in the sand' defense to actions for securities fraud committed on their watch").

[34] The Individual Defendants (Br. at 11) contend that because no management failures were reported on the Forms 483, no such failures may be inferred. This is a red herring, because Plaintiffs are not alleging mismanagement; they are alleging that Defendants misrepresented and failed to disclose adverse facts. *See supra* n.22. In any event, given Defendants' admissions that the problems at Allston were the result of "systemic" causes, requiring "fundamental systemic and cultural changes" to Genzyme's compliance programs, ¶170, and given that Genzyme ultimately entered a consent decree based on the observations in the November 2009 483 – which were essentially the same problems as has been noted in the October 2008 483, ¶¶192, 193 – the argument that there were no failures of management is nonsensical.

Moreover, pursuant to standard industry procedures, Allston's plant managers would have updated senior Genzyme executives every day during the FDA inspections of Allston as to any issues raised by the FDA. ¶332. It is also standard procedure in any drug manufacturing company to hold meetings among its high-level executives, in particular those directly tasked with QA and regulatory compliance duties, to discuss any communications with the FDA. ¶334. Here, defendants Lawton and Meeker in particular were directly responsible for overseeing quality control and regulatory affairs, were made aware of the FDA's observations, and were in contact with the FDA throughout the Class Period. *Id.* Therefore, they knew that the supply of Genzyme's drugs was at risk and that Allston's GCMP violations jeopardized Genzyme's ability to obtain approval of Lumizyme. ¶332. *See Boston Sci.*, 523 F.3d at 91 (scienter alleged where "[t]he company said it had been monitoring, analyzing, and investigating the problem"); *Shaw*, 82 F.3d at 1224 n.38 ("plaintiffs' allegations of a 'highly-efficient reporting system'... speak[s] to the question of *how* defendants might have known what they allegedly knew").

c. The Materiality of the CGMP Deficiencies Supports Finding Scienter

The CGMP compliance problems at Allston were not minor issues that could have escaped Defendants' notice. These issues permeated virtually every area of manufacturing, ¶¶55-82, including failure to maintain proper equipment, failure to monitor for contamination, mishandling of raw materials, failure to train employees, and inadequate or manipulated testing for quality control. Genzyme received from the FDA two lengthy Forms 483, a Warning Letter, and a letter notifying it of a *third* FDA inspection in less than one year, all of which were replete with descriptions of Genzyme's unremedied CGMP violations. ¶¶10, 15, 88, 98-99, 101, 112-113, 162, 183-186. These were not run-of-the-mill regulatory interactions: Form 483s are issued for "significant objectionable conditions," ¶46, and FDA warning letters are only issued for "significant regulatory violations that require prompt and adequate corrective actions." ¶47. Nonetheless, as evidenced by the post-Class Period FDA complaint and the $175 million Consent Decree, Defendants failed to heed these warnings and cure its CGMP deficiencies,

despite knowing that CGMP compliance was necessary to obtain FDA approval of Lumizyme.[35] In *Dendreon*, 2008 WL 5130042, at *7-8, finding that where Form 483 issues could delay approval of a drug application, allegations that the issues remained unresolved for more than a year created a cogent and compelling inference of scienter.

Also during the Class Period, Genzyme experienced ***three major and highly-unusual viral contamination events: one in Geel, Belgium and two at Allston in less than one year.*** ¶¶14, 84, 95-96, 104-105, 139, 180-181. Indeed, the problems at Allston were sufficiently severe that Genzyme secretly decided to abandon its plans to manufacture Lumizyme that it had been touting since at least 2007, ¶¶125-126, 153, and was forced to transfer other significant operations out of Allston altogether in the wake of a *third* contamination outbreak there in November 2009. ¶¶198, 204. And if there were any remaining doubt about the extent of the problems at Allston, in May 2010 Genzyme entered into a $175 million Consent Decree with the FDA, and agreed to have an outside monitor supervise a *2-3 year* remediation plan.

The sheer magnitude of these problems – located in the Company's most important manufacturing facility – supports a strong inference that they were known to the Company's top officers. *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 77 (2d Cir. 2001) (large write-off "undermines, at the pleading stage, the argument that defendants were unaware of the [problems] until shortly before [announcing the charges]"); *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000) (same); *In re Royal Ahold N.V. Sec. ERISA Litig.*, 351 F. Supp. 2d 334, 376 (D. Md. 2004) (massive, pervasive nature of fraud "serves to amplify the inference of scienter" by corporate executives) (citation omitted); *Rehm v. Eagle Fin. Corp.*, 954 F. Supp. 1246, 1256 (N.D. Ill. 1997) ("The more serious the error, the less believable are defendants' protests that they were completely unaware of [the company's] true financial status ..."). As the court put it in *In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 216 (D. Mass. 2001), "there is a link

[35] Genzyme's public filings acknowledged that "[a]s part of product approval, the manufacturer of the product must undergo a pre-approval Good Manufacturing Practices inspection ..." ¶¶45, 336.

between scienter and materiality. The more material the omission, the more it might be thought to have been purposefully motivated by an intent to deceive."[36]

d. Defendants Had Motive And Opportunity To Commit Fraud

Defendants assert that the Complaint alleges no motive for them to lie to the investing public. (Indiv. Def. Br. at 12, 14; Genzyme Br. at 2, 4, 15). As a threshold matter, Plaintiffs *are not required* to plead motive in order to allege scienter. *See Tellabs*, 551 U.S. at 325 ("the absence of a motive allegation is not fatal."); *Aldridge*, 284 F.3d at 82 (same). "As long as the inference of scienter from Plaintiffs' [] Complaint is 'at least as compelling as any opposing inference of nonfraudulent intent' it does not matter whether any one or more or all of the Defendants personally derived a benefit from the alleged scheme." *In re Huffy Corp. Sec. Litig.*, 577 F. Supp. 2d 968, 991 (S.D. Ohio 2008) (internal citation omitted). Nevertheless, averments that a defendant possessed motive and opportunity to defraud can *strengthen* the inference of scienter. *Aldridge*, 284 F.3d at 82; *ACA Fin. Guar. Corp.*, 512 F.3d at 67.[37]

Motive may be alleged through facts showing "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged," *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1130 (2d Cir. 1994), including "the self-interested motivation of

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[36] Moreover, even before the Class Period, the FDA had warned Genzyme on multiple occasions that it lacked adequate controls over manufacturing, including in warning letters in 2001 and September 2007. ¶9. The 2001 warning letter, addressed to Termeer, expressly warned: "[T]he specific violations … may be symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA." ¶327. Among the observations in the 2007 warning letter was that Genzyme had continued manufacturing a drug despite excessive bacteria levels in early batches, and had not adequately investigated the problem, such that there was a "high probability that the observed CGMP deviations, if not corrected, would substantially increase the risk of future product failures." ¶328. The 2007 letter also noted that the FDA had routinely found contaminants (such as mold) at the Lyon, France facility since 2004.

[37] Defendants cannot and do not dispute that they had the opportunity to commit fraud. The Individual Defendants were the highest-ranking officers of the Company, and made numerous public statements on analyst conference calls and/or in SEC filings which they reviewed and signed. ¶¶25-32, 216-320. *See Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001) ("[I]t is undisputed that the individual defendants, as Directors of MediaOne, had the opportunity to commit fraudulent acts.").

defendants in the form of saving their salaries or jobs." *Greebel*, 194 F.3d at 196. Under these standards, the Complaint plainly describes Defendants' motives to lie to investors.

First, Myozyme/Lumizyme was the most critical product in the Company's inventory, and the Company was anxious to obtain FDA approval. Admission of the true situation at Allston would—as it ultimately did—render that goal dead on arrival.

Second, serious competition was looming, and the longer Defendants withheld the truth from investors and consumers, the longer they could stave off a loss of market share. ¶¶40, 86, 87. In fact, as Genzyme continued to struggle with its manufacturing and compliance issues, its competitors Shire and Protalix gained ground. ¶¶205-214. Motive to keep away the competition supports a strong inference of scienter. *See, e.g.*, *Boston Sci.*, 523 F.3d at 88-89 (motive to maintain market share for medical device supports an inference of scienter); *Zoll Med. Corp.*, 1996 WL 392146, at *10, n.26 (motive to downplay FDA compliance problems so as to appear to be on equal footing with competitor supported an inference of scienter).

Third, Defendants were motivated to conceal material information about the CGMP problems in order to avoid a loss of confidence, both from consumers (who would question the safety of Genzyme's products), and from investors (who would question the prospects for Genzyme's growth and profitability). ¶337. Such a motive supports an inference of scienter. *See Warshaw*, 74 F.3d at 959-60 (statements regarding safety of company's new products were actionable as they "were designed to prevent shareholder flight in the aftermath of a damaging report regarding the possible hazards of [the product] and the unlikelihood of FDA approval").

Fourth, the Individual Defendants had personal motives to conceal the truth about Allston. Disclosing the truth would have jeopardized Termeer's continued reign as Genzyme's CEO – a position that brought with it a lucrative salary and perks, including use of Genzyme's corporate jet. ¶25. Indeed, in the wake of the problems at Allston, one analyst dubbed Termeer the worst CEO of the year, and accused the Company of "whitewash[ing]" problems and "hoping they either go away or can be disguised so well that no one notices." ¶215. The analyst

further described how Termeer facilitated Genzyme's collapse by "foster[ing] an arrogant, irresponsible business culture in which employees are rewarded more for being loyal to the CEO than they are for being competent at their jobs." *Id.* Such comments support an inference that other Genzyme officers, including the Individual Defendants, were motivated to "toe the line" by not contradicting their imperious boss, even if it meant being complicit in fraud, because they also wished to preserve their jobs and salaries.[38] *See Greebel*, 194 F.3d at 196.

In the face of these allegations, Defendants contend that they had no motive to lie because the truth would eventually come out (Indiv Br. 13). Courts, however, routinely reject such post-hoc rationalizations, and it is certainly plausible to infer that Defendants sought to delay their day of reckoning, perhaps in the hope that they would be able to fool the FDA inspectors into believing that cosmetic "quick fixes" were enough, or that (as recently reported in the press) they could negotiate an "exit strategy" in the form of a buyout by a larger drug company before they would be held responsible for the Company's rampant compliance deficiencies. *See Makor*, 513 F.3d at 710 ("The fact that a gamble – concealing bad news in the hope that it will be overtaken by good news – fails is not inconsistent with its having been a considered, though because of the risk a reckless, gamble. It is like embezzling in the hope that winning at the track will enable the embezzled funds to be replaced before they are discovered to be missing."). The securities laws do not permit Defendants to make false assertions in the "blind hope" that they will eventually become truthful. *In re Pozen*, 386 F. Supp. 2d 641, 646; (M.D. N.C. 2005) *see also Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 728 (7th Cir. 2004) ("[T]he truth was bound to come out quickly, but the securities laws forbid foolish frauds along with clever ones").

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[38] To the extent Defendants assert that the purported absence of insider stock sales goes against a finding of scienter (Indiv. Def. Br. at 12), they are mistaken. While allegations of insider sales may establish motive, their *absence* does not defeat a finding of scienter. *See, e.g., Am. W.*, 320 F.3d at 944 ("the lack of stock sales by a defendant is not dispositive as to scienter"); *In re Metawave Commc'ns Corp. Sec. Litig.*, 298 F. Supp. 2d 1056, 1071 (W.D. Wash. 2003) ("Scienter can be established even if there were no sales of stock by officers during the class period.").

e. The Complaint Does Not Assert "Fraud By Hindsight"

Defendants accuse Plaintiffs of impermissibly pleading "fraud by hindsight."[39] However, Plaintiffs do *not* simply rely on conclusory pleadings that Defendants "must have known" that Lumizyme would not be approved, or that revenues from Cerezyme and Fabrazyme would become compromised. The basis of Plaintiffs' claims is that Defendants knew or were severely reckless in not knowing, *at the time they made their public statements*, numerous facts – including that Genzyme was plagued with pervasive CGMP deficiencies – that rendered Defendants' statements regarding the Company, its financial prospects and the status of its Lumizyme BLA materially false and misleading. Where the complaint creates an inference that defendants had knowledge of contrary facts as of the time the allegedly false statements were made (including, as here, Defendants' own admissions and the sheer magnitude of the problems centering on Genzyme's most core operations), there is no "hindsight." *See Boston Sci.*, 523 F.3d at 90-91 (complaint did not plead fraud by hindsight, given evidence "that defendants knew earlier what they chose not to disclose until later"); *In re Smith & Wesson Corp. Sec. Litig.*, 604 F. Supp. 2d 322, 343 (D. Mass. 2009) (allegation that defendants knew that projections were inflated at the time they projected high revenue growth was not fraud by hindsight); *Sloman*, 2007 WL 2740047, at *8 (no fraud by hindsight where complaint alleged facts supporting a strong inference that when executives made public statements regarding revenues, they knew of material reasons for doubting the previous revenue projections).[40]

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[39] *See* Genzyme Br. at 19, 33-35; Indiv. Def. Br. at 1, 12, 14. Under the fraud by hindsight by doctrine, general allegations "that defendants knew earlier what later turned out badly" are not sufficient to plead scienter. *Ezra Charitable Trust v. Tyco Int'l,* 466 F.3d 1, 6 (1st Cir. 2006). The First Circuit has cautioned courts to apply the doctrine sparingly so as to not pre-emptorily "cut off the case as a matter of law, without further factual development." *Boston Sci.*, 523 F.3d at 90.

[40] Conversely, in *In re Praecis Pharms., Inc. Sec. Litig.*, 2007 WL 951695 (D. Mass. Mar. 28, 2007), on which Defendants rely (Indiv. Def. Br. at 13; Genzyme Br. at 33-34), the plaintiffs failed to plead *any* allegations that defendants knew their statements were false when they made them. *Id.* at *5-17. And unlike *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145 (D. Mass. 2009) or *Discovery Labs.*, 2007 WL 789432 at *5 (Genzyme Br. at 33-34), Plaintiffs' scienter allegations are grounded on more than the assertion that because something came to pass, Defendants must have known of its eventuality when they made the allegedly false statements.

2. Plaintiffs' Strong Inference of Scienter Is Not Outweighed by Any Plausible Opposing Exculpatory Explanation

Defendants try mightily to conjure up an alternative, non-fraudulent explanation for their conduct. Specifically, Defendants argue that Plaintiffs' theory of fraudulent concealment is implausible in light of the fact that, at times during the Class Period, Defendants made certain disclosures which they claim revealed "much" of the information that the Complaint alleges was concealed. (Genzyme Br. at 4, 16, 27; Indiv. Def. Br. at 13-15).

First, what they cite as publicly disclosed — the receipt of the October 2008 483, the Warning Letter, the "bioreactor failures," and delays in approval dates set by the FDA — were not disclosed by Genzyme until it was clear that they were going to become public knowledge anyway. For example, the February 2009 Warning Letter was issued in tandem with the FDA's first refusal to approve Lumizyme, and specifically mentioned the October 2008 483. Because Defendants had been publicly assuring investors that Lumizyme would be approved, and because warning letters are typically posted on the FDA website,[41] these facts could no longer be concealed. Indeed, the more telling point is that Defendants waited five months to disclose the October 2008 483, even as they continued to assure investors of Lumizyme's imminent approval, and only disclosed it when it was mentioned in the Warning Letter. Far from showing lack of scienter, Defendants' belated disclosure of this information merely reflects their conscious decision to try to avoid any disclosure of adverse facts until such disclosure was inevitable.

Second, as discussed above, what Defendants point to as disclosures still did not reveal the myriad material facts alleged throughout the Complaint regarding the extent of the manufacturing compliance deficiencies and Genzyme's inability to catch up in time and fix them without depleting inventory and jeopardizing the BLA application. The cases Genzyme cites

[41] *See* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm.

(Br. at 17-18, & n. 8) do not support their "plausibility" theory because, in each one, the disclosures were far more fulsome than any Defendants made here.[42]

Similarly, that Defendants communicated with the FDA does not mean they lacked an intent to deceive investors. (Genzyme Br. at 17-18). Disclosure to the FDA is not the same as disclosure for purposes of the securities laws. *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 636-37 (S.D.N.Y. 2008) (rejecting defendants' contention that, because they disclosed the adverse studies of a drug product to the FDA, they did not conceal them in violation of any obligations imposed by the securities laws). *Indeed, information disclosed only to the FDA is generally not available to investors absent a FOIA request*, and an investor would have no reason to make such a request absent some cause to suspect that there were material adverse facts that the Company had disclosed only to the FDA.

Moreover, in arguing that it is plausible they did not act with scienter, Defendants improperly argue their version of disputed facts, and ask the Court to draw disputed factual inferences in their favor – which is not proper on a Rule 12(b)(6) motion. *See Tellabs*, 551 U.S. at 326 (averments must be "accepted as true and taken collectively"); *ACA Fin.*, 512 F.3d at 58. For example, Defendants cite to a January 16, 2009 press release (McL. Decl. Ex. K) for the sweeping factual proposition that Genzyme "*routinely* communicated with regulators regarding the manufacturing problems it had experienced at Geel and Allston" (Genzyme Br. at 17; emphasis added). Citing to a vague statement of "manufacturing problems at Genzyme

[42] In *Horizon Asset Mgmt., Inc. v. H&R Block, Inc.*, 580 F.3d 755 (8th Cir. 2009), senior management willingly disclosed corporate accounting control failures as they became aware of the problems. Here, in stark contrast, Defendants purposely *withheld* disclosure of manufacturing problems. In *Iron Workers Local No. 25 Pension Fund v. Oshkosh Corp.*, 2010 WL 1287058 (E.D. Wis. Mar. 30, 2010), the plaintiffs' sole complaint was that the company should have taken a goodwill impairment charge upon its acquisition of another company, but they also conceded that the defendants repeatedly disclosed that they tested for goodwill impairment and, once they discovered a basis to take the charge, they timely did so. In other words, the defendants at all times complied with accounting practices. Here, the Complaint alleges that at all times, Defendants *deviated* from applicable manufacturing practices. In *In re The First Marblehead Corp. Sec. Litig.*, 639 F. Supp. 2d 145 (D. Mass. 2009), *Gaines v. Guidant Corp.*, 2004 WL 2538374 (S.D. Ind. Nov. 8, 2004) and *In re Brightpoint, Inc. Sec. Litig.*, 2001 WL 395752 (S.D. Ind. Mar. 29, 2001), the companies disclosed the very thing which the complaints alleged they concealed. Defendants at bar do not assert that they revealed everything that Plaintiffs allege was concealed.

facilities" in the same press release, Defendants argue – contrary to fact – that the investing public was somehow specifically informed of ***contamination*** problems at Allston and Geel in 2008. In fact, investors were only warned of hitches in the "normal development process" for new plants with respect to Geel, ¶271, and were *never* told of the November 2008 Allston contamination until June 2009 – after the plant had been forced to shut down entirely as a result of yet *another* contamination outbreak of the *same* virus at the *same* facility. Defendants' pre-2009 disclosures were thus facially insufficient to inform investors of *any* problems at Genzyme and, as shown above, their later disclosures utterly failed to fully or completely disclose the "systemic and fundamental" nature of the problems it belatedly did admit it was experiencing.

Defendants also assert – contrary to the Complaint – that the October 2008 483 observations had nothing to do with the Lumizyme manufacturing process or the June 2009 contamination. (Genzyme Br. at 30, 31). This flatly contradicts Plaintiffs' allegations, which must be accepted as true. ¶¶98-102, 142, 144, 162, 170, 183-87, 304-10. Defendants will have an opportunity to argue their version of the facts, but they may *not* do so on a motion to dismiss.

Even were Defendants' factual arguments permitted on a motion to dismiss, they would not warrant dismissal because Defendants' proposed inferences – to the effect that they made *some* disclosures to the FDA (and fewer still to the public), and purportedly believed they did not have to make any more – are no *more* compelling than the inference that Defendants repeatedly sought to delay disclosures as long as possible, and then – when they finally felt compelled to make partial disclosures of "some" problems – continued to conceal the truth and deceive investors by downplaying any problems and falsely assuring that any deficiencies – if not already fully remedied – were capable of being, and would be, fixed promptly. *See Dendreon*, 2008 WL 5130042, at *7 (finding inference of fraud at least as plausible as defendants' argument that they withheld the existence of the Form 483 because the problems were not serious, or because they supposedly believed the problems could easily be remedied in time to gain FDA approval of their drug); *In re Schering-Plough Corp./Enhance Sec. Litig.*, 2009 WL 2855457 (D.N.J. Sept. 2,

2009) (allegations that defendants deliberately concealed negative results of drug study was "at least as compelling" as defendants' proposed inference that delay in announcing those results was justified by their attempts to rectify data quality problems).

Plaintiffs' allegations, construed as a whole, amply support the requisite strong inference that Defendants knowingly or recklessly concealed Genzyme's CGMP problems from investors and misled investors regarding the prospects for approval of Lumizyme, and that inference is at least as compelling as any alternative inference that may be drawn from those allegations.

D. Genzyme is Not Protected by the PSLRA Safe Harbor

The PSLRA contains a "safe harbor" that provides that liability will not be imposed on forward-looking statements that are "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or that are not made with "actual knowledge" that the statement "was false or misleading." 15 U.S.C. § 78u-5(c)(1). The First Circuit has described the statute as creating the "surprising rule that the maker of knowingly false and willfully fraudulent forward-looking statements, designed to deceive investors, escapes liability for the fraud" if the statement contains sufficient cautionary language. *Stone & Webster*, 414 F.3d at 212. The First Circuit cautions that "this curious statute, which grants (within limits) a license to defraud" must be subject to a restricted interpretation. *Id.* None of Defendants' statements meets the preconditions for safe harbor protection.[43]

[43] Genzyme, citing *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953 (D. Md. 1995), *In re PLC Sys., Inc. Sec. Litig.*, 41 F. Supp. 2d 106 (D. Mass. 1999), and *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549 (S.D.N.Y. 2004), suggests that all forward-looking statements predicting approval of Lumizyme are *per se* inactionable because they were not worded as "guarantees." This is plainly not the law: the PSLRA explicitly makes forward-looking statements actionable, whether or not worded as guarantees, which is why the cases cited by Genzyme are in the extreme minority. *See Amylin*, 2003 WL 21500525, at *8 n.3 (rejecting *Medimmune*); *Sepracor*, 308 F. Supp. 2d at 34 n.9 (same); *Irvine v. ImClone Sys.*, 2003 WL 21297285 (S.D.N.Y. June 3, 2003) (sustaining complaint based on statements concerning the same drug application that formed the basis for the claims in *Bristol Myers*). Moreover, even if some kind of assurance of success were necessary to render Defendants' statements actionable, here such statements as "We have a PDUFA date by the 28th of February [and] will again get the 2000L profusion reactor system approved," (¶269), are sufficiently definite to trigger liability.

1. Most of Genzyme's False Statements Were Not Forward-Looking

The safe harbor only protects "forward-looking" statements. *Stone & Webster,* 414 F.3d at 213. "In analyzing a forward-looking statement, the aspect of the statement that is based on the present fact must be distinguished from the aspect of the statement that is a future projection. "The safe harbor ... is intended to apply only to allegations of falsehood as to the forward-looking aspects of the statement." *Biogen IDEC*, 537 F.3d at 45 n.13; *accord Shaw,* 82 F.3d at 1219 (cautionary language does not protect false "representation of present fact").

Most of the statements alleged to be false here concern present and historical facts, rather than the future. For example, Defendants misrepresented Genzyme's *present* intention to market Lumizyme commercially in the U.S., even after Genzyme had decided internally that it would not market the drug. *See* ¶¶125-6, 280, 283, 314. False representations of a company's current plans are not protected as "forward-looking." *See Harden v. Raffensperger, Hughes & Co.*, 65 F.3d 1392, 1405-06 (7th Cir. 1994). Similarly, when Genzyme claimed it was "on track" and "on schedule" for meeting FDA requirements and obtaining approval of Lumizyme (*e.g.* ¶¶270, 294, 318), or that the "growth potential" for the LSD segment was "strong" (¶263; *see also* ¶217 ("a very, very strong picture *is* unfolding") & ¶249 (describing past quarter as "extremely productive in terms of building for the future" without disclosing Geel contamination or that it had just received October 2008 483)), Defendants misrepresented Genzyme's *current* status. *See, e.g., Capri Optics Profit Sharing v. Digital Equip. Corp.*, 950 F.2d 5, 11 (1st Cir. 1991) ("We're well poised to go into [the third quarter]" is representation of present condition); *Amer. West.*, 320 F.3d at 936 ("We are not anticipating any major increase in maintenance costs or the cost of oversights" is not forward-looking); *In re Secure Comp. Corp.*, 184 F. Supp. 2d 980, 990-91 (N.D. Cal. 2001) (statement that company is "on track" to meet expectations is a statement of current business conditions); *Silverman v. Motorola, Inc.*, 2008 WL 4360648, at *10 (N.D. Ill. Sept. 23, 2008) (same). Similarly, statements referring to, *e.g.* (a) conditions at Allston including its "extensive sterile filling capacity" (¶¶239, 255, 285); (b) "tight Myozyme supplies" and large

write-offs for product losses (which were misleadingly attributed only to "incomplete validations runs" and "normal start-up costs," rather than abnormal contamination issues) (¶¶266, 271-2, 291, 296); (c) the purported resolution (or virtual resolution), pursuant to purportedly "complete" remedial plans, of all compliance issues identified in the belatedly disclosed October 2008 483, and the adequacy of Genzyme's compliance documentation (¶¶278-79, 289, 294, 299, 302, 306, 310, 316); and (d) how Defendants (despite running the aging and non-compliant Allston plant at more than 100% capacity) were purportedly "managing the company in a very conservative manner" (¶292), were all statements of *present* or historical fact.

2. Defendants Had Actual Knowledge Of Their Statements' Falsity

A statement projecting future events contains three implicit factual assertions: "(1) that the statement is genuinely believed; (2) that there is a reasonable basis for that belief; and (3) that the speaker is not aware of any undisclosed facts tending to seriously undermine the accuracy of the statement." *Helwig v. Vencor, Inc.*, 251 F.3d 540, 557 (6th Cir. 2001) (en banc) (quoting *In re Apple Comp. Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989)); *Sepracor*, 308 F. Supp. 2d at 33-34. Thus, to have "actual knowledge" of falsity, a defendant must know that one of those three assertions is false, *i.e.*, he must not genuinely believe the statement, must know that there is no reasonable basis for the statement, *or* must be aware of undisclosed facts that seriously undermine the accuracy of the statement. *See Slayton v. Am. Express Co.*, 604 F.3d 758, 774 (2d Cir. 2010) (citing *Apple Computer*, 886 F.2d at 1113; Brief for SEC as Amicus Curiae at 12).

Here, Plaintiffs allege facts showing that Defendants did not believe their statements, had no reasonable basis for believing them, and/or were quite aware of undisclosed facts that undermined their accuracy. For example, Plaintiffs allege how Defendants (a) privately *admitted* during the Class Period (and again later) that they knew that compliance deficiencies at Allston during the relevant period were "systemic" and "fundamental" (¶¶170, 191-95); and (b) knew the results of FDA inspections, but *never* developed plans to fully remedy the deficiencies, failed to implement various measures they had promised the FDA they would undertake, and knew that

any effective remedial plan would require fundamental changes that were incapable of quick fixes. ¶¶100-02, 162, 170, 202. Similarly, Termeer admitted that Defendants knew in March 2009 that Allston could not handle the burden of producing Lumizyme, even as they continued to tell investors that they expected to start generating revenues from U.S. sales of Lumizyme in 2009 from an FDA-approved production line at Allston. ¶¶199, 280, 283, 292, 299, 305, 308, 312. Factual allegations far less damning than these are routinely found to adequately allege "actual knowledge" of falsity in the safe harbor context. *See, e.g.*, *Sepracor*, 308 F. Supp. 2d at 34 ("actual knowledge" exists where defendants knew their drug application did not comply with FDA requirements for approval); *Amgen*, 544 F. Supp. 2d at 1029 (company deemed to have "actual knowledge" that drug would not be approved when it knew it had not taken actions required by FDA).[44] For the same reasons, Defendants had actual knowledge of "undisclosed facts tending to seriously undermine the accuracy" of their projections for growth generally (and for Genzyme's LSD segment in particular), given their knowledge of conditions at Allston, and of the depleted Cerezyme and Fabrazyme inventories.

Defendants contend that Plaintiffs have not "established" that they knew for certain that Genzyme could not meet its projections or that the Lumizyme BLA would be rejected, and therefore have not established "actual knowledge."[45] However, "[a]lthough the PSLRA was enacted to end the practice of pleading fraud by hindsight, the PSLRA does not require that Plaintiffs show that Defendants were capable of predicting the future." *Yanek*, 388 F. Supp. 2d at 1130. Thus, even though Defendants "may have believed or hoped that the issues raised in the Form 483 would not pose a serious problem to FDA approval[,] ... [their] failure to mention

[44] In a footnote, Genzyme (Br. at 37, n.28) contends there has been no showing that "Genzyme had information that seriously undermined the accuracy of its statements" because an FDA advisory committee recommended approval of Lumizyme based on evidence of *clinical efficacy*. The committee's findings on clinical efficacy, however, are irrelevant to Plaintiffs' claims that Defendants misled investors as to conditions at the manufacturing facility (Allston) where Lumizyme was to be made – which, as Defendants knew, is also a required component of a BLA.

[45] Genzyme (Br. at 29) also argues that Plaintiffs cannot show that Defendants "knew" the PDUFA dates would change. But as noted *infra* at § E.1, this argument dodges the relevant point: the fraud did not consist of misstating PDUFA dates, but of misrepresenting what the FDA would likely *do* on those dates.

those issues in their statements responding to direct questioning about potential obstacles to FDA approval raises a strong inference that those statements were made with actual knowledge of their falsity." *Id.* at 1132; *cf. Pozen*, 386 F. Supp. 2d at 646 (optimistic statements regarding FDA approval must be based on something other than "blind hope").

3. Any Purported Cautionary Language Was Inadequate

Defendants, *not* Plaintiffs, bear the burden of showing that any cautionary language is "meaningful" under the PSLRA. *Slayton*, 604 F.3d at 772. The First Circuit has noted that the PSLRA codified the prior judge-made "bespeaks caution" doctrine. *Shaw*, 82 F.3d at 1213, n.23; *Fisher v. SpecTran Corp.*, 2001 WL 34644311, *4 n.5 (D. Mass. May 31, 2001). Under that doctrine, a false forward-looking statement cannot form the basis of a fraud claim if it is accompanied by cautionary disclosures that render it "immaterial as a matter of law." *Shaw*, 82 F.3d at 1213. Dismissal based on cautionary language is appropriate "only when reasonable minds could not disagree as to whether the *mix* of information in the [statement at issue] is misleading." *Id.* at 1214 (quoting *Fecht v. Price Co.*, 70 F.3d 1078, 1082 (9th Cir. 1995)).[46]

Courts consider several factors to assess whether cautionary language is "meaningful." First, cautionary words about future risk cannot insulate from liability the failure to disclose risks that have *already* transpired. *Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004); *see also Slayton*, 604 F.3d at 770 ("cautionary language that is misleading in light of historical fact cannot be meaningful") (citation omitted). As one court put it in an oft-quoted phrase, there is "no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away." *In re Prudential Sec. Inc. P'ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996).[47]

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[46] *See also Rosenbaum Cap. L.L.C. v. Boston Comm. Grp., Inc.*, 445 F. Supp. 2d 170, 177 (D. Mass. 2006) (same); *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 252 (D. Mass. 2006) (same).

[47] *See also Rombach*, 355 F.3d at 173 (the bespeaks caution doctrine "may not be abused or gamed"); *Dolphin & Bradbury, Inc. v. SEC*, 512 F.3d 634, 640 (D.C. Cir. 2008) (cited with approval in *Slayton*) (noting a "critical distinction between disclosing the risk a future event might occur and disclosing actual knowledge the event will occur").

Second, "cautionary statements must be substantive and tailored to the specific future projections." *Semerenko v. Cendant Corp.*, 223 F.3d 165, 182 (3d Cir. 2000); *Schaffer v. Timberland Co.*, 924 F. Supp. 1298, 1316 (D.N.H. 1996) (same). "Vague or boilerplate disclaimers are insufficient to invoke safe harbor protection." *Sepracor*, 308 F. Supp. 2d at 34.

Third, the cautionary language must realistically communicate both the ***magnitude*** of the risk and its ***severity***. *See, e.g.*, *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 248 (5th Cir. 2009) ("The omission of a known risk, its probability of materialization, and its anticipated magnitude, are usually material to any disclosure discussing the prospective result from a future course of action."); *In re Boston Tech. Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 53 (D. Mass. 1998) ("cautionary language must be sufficiently … strong in tone to counter the statement made"); *Prudential*, 930 F. Supp. at 72 ("even apparently specific risk disclosures" may be misleading if internally the company recognizes that the risks are "significantly greater or more certain" than disclosed).[48]

Fourth, valid cautionary language must adjust as risks loom larger. *See Slayton*, 604 F.3d at 772-73 (defendants' cautionary language insufficient where it "remained the same even while the problem changed"); *Baxter*, 377 F.3d at 734 (faulting cautionary language that "remained fixed even as the risks changed"); *Helwig*, 251 F.3d at 559 (cautionary language insufficient where it remained "substantially" the same over several years even as "warning signs flared"). These requirements are necessary to ensure that an issuer does not just "list its lines of business, say 'we could have problems in any of these,' and avoid liability for statements implying that no such problems were on the horizon even if a precipice was in sight." *Baxter*, 377 F.3d at 734.

Genzyme's cautionary language was not "meaningful." Prior to disclosure of the February 2009 Warning Letter, Genzyme's "warnings" consisted of variations on the banal observation that it might not be able to obtain FDA approval. *See, e.g.*, Genzyme Attachment 2

[48] *Cf. Pommer v. Medtest Corp.*, 961 F.2d 620, 624 (7th Cir. 1992) ("It is not enough that the other party must have recognized a risk. Risks are ubiquitous. Disclosures assist investors in determining the magnitude of risks.").

at 3 ("These statements are subject to risks and uncertainties [such as] our ability to secure regulatory approvals for our products, services and manufacturing facilities, and to do so in the anticipated timeframes, including our ability to obtain and maintain regulatory approvals for Myozyme produced at the 2000L scale in the [U.S.] and ... 4000L scale in Europe"). Such "warnings" are the functional equivalent of Genzyme telling investors that FDA approval of the Lumizyme BLA is expected unless the FDA does not approve the BLA – which is precisely the sort of "circular" warning that courts routinely reject as not meaningful. *See Slayton*, 604 F.3d at 772 (rejecting cautionary language as "boilerplate" because it "essentially warn[s] that 'if our portfolio deteriorates, then there will be losses in our portfolio.'"); *Yanek*, 388 F. Supp. 2d at 1123 (cautionary language inadequate where it could apply to "literally any issuer subject to FDA regulation").[49] Similarly, "warnings" that Genzyme might be unable to "successfully scale-up production" of its drugs were hardly sufficient to warn that it had *already* cut back on production of Cerezyme and Fabrazyme, and was running Allston well beyond its capacity, even as it touted the "growth potential" of its LSD segment. *See Lormand*, 565 F.3d at 247 (cautionary language insufficient for failing to disclose that risks had already begun to materialize).[50] Moreover, nothing in Genzyme's warnings suggested that the ***magnitude*** of the risks associated with its CGMP (non-)compliance were ***remotely*** as large as they actually were.

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[49] *See also Amylin*, 2003 WL 21500525, at *8 (insufficiently specific to warn only that "Results from our clinical trials may not be sufficient to obtain regulatory clearance"); *ImClone*, 2003 WL 21297285 at *1 (insufficient to warn that "[n]oncompliance with applicable requirements can result in refusal to approve product licenses or other applications," and that there are "risks and uncertainties associated with completing pre-clinical and clinical trials ... [and] obtaining and maintaining regulatory approval for such compounds").

[50] These omissions were particularly glaring given that the Company did highlight such other specific problems as the FDA's conclusion that the 2000L material was not similar to the 160L material, and potential stumbling blocks regarding data on safety and efficacy (Def. Attachment 2 at 8-9, Attachment 3 at 5-6) – neither of which concerned the Company's deficient manufacturing practices. *See Baron,* 285 F. Supp. 2d at 102 ("[E]mphasis and gloss, can, in the right circumstances, create liability."); *Halperin v. EBankerUSA.com*, 295 F.3d 352, 360 (2d Cir. 2002) (issuers may not "gloss over the relevant risk, focus investors' attention elsewhere, and thereby lead them down some primrose path").

Genzyme's cautionary language was also insufficient because it did not change or even mention potential CGMP problems after two viral contaminations and the receipt of the October 2008 483 (*see, e.g.*, Def. Attachment 2 at 6-7 (referring investors to the cautionary language drafted before the first contamination and before the October 2008 483); *id.* at 7-8 (cautionary language omits any mention of compliance issues)) – even though those events dramatically increased the risk that Lumizyme would not be approved and that Genzyme would not meet its projections. Genzyme simply continued to warn of the *possibility* that the FDA would reject its Lumizyme BLA while failing to disclose that FDA inspectors had *already* issued a report indicating that Genzyme did not meet preconditions for approval. *See In re Regeneron Pharms., Inc. Sec. Litig.*, 2005 WL 225288, at *19 (S.D.N.Y. Feb. 1, 2005) (in context of a new drug application, "discussing hypothetical risks that might occur in the future does not adequately disclose actual problems that already have materialized;" finding warnings insufficient where they did not "refer to any of the specific problems concerning" the new drug application).[51] Similarly, as in *EVCI Colleges*, the safe harbor does not protect a company that projects increased revenue while it is "out of regulatory compliance." 469 F.Supp. 2d at 103. As the court explained, such facts defeat the safe harbor "not because defendants did not identify the correct risk factors, but because the disclosures failed to warn investors that the risk factors were not hypothetical – which, of course, dramatically increased the possibility of adverse consequences." *Id.* at 102-103.[52]

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[51] *See also Apple*, 886 F.2d at 1115 ("There is a difference between knowing that any product in development may run into a few snags and knowing that a particular product has already developed problems....."); *Amylin,* 2003 WL 21500525, at *8 (warnings that FDA might reject the application "did not provide meaningful information to the plaintiffs regarding the FDA's concern"); *Yanek*, 388 F. Supp. 2d at 1123 (insufficient to merely warn of the "need to obtain regulatory approval for new products"; instead, company was required to discuss "factors related to its existing manufacturing facilities").

[52] Nor can Genzyme avoid liability by generically "warning" investors "not to place substantial reliance" on their statements. Def. Attach. 2 at 9. *See, e.g., In re Nat'l Century Fin. Enters. Inv. Litig.*, 541 F. Supp. 2d 986, 1005 (S.D. Ohio 2007) ("general disclaimers of accuracy do not shield sellers who knowingly make false statements") (citing §29(a) of the 1934 Act).

Even after disclosure (in March 2009) of the October 2008 483 and the February 2009 Warning Letter, Defendants continued to offer warnings that mostly restated the obvious fact that Genzyme might not obtain FDA approval (*see* Def. Attach. 2 at 13, 15-16), supplemented only by equally generic "warnings" that Genzyme might not be able to satisfy the concerns expressed in the Warning Letter (*see* Attach. 3 at 9-11). But such new "warnings" had the same meaningless circularity as Genzyme's earlier warnings (*see, e.g., Slayton, supra*), and omitted "hard facts critical to appreciating the magnitude of the risks described," *Nortel Networks*, 238 F. Supp. 2d at 629 n.15, such as the pervasiveness, severity and systemic nature of the problems at Allston, or the fact that Defendants had secretly determined in March 2009 that Allston was stretched too thin to be able to produce commercial quantities of Lumizyme for sale in the U.S. *See Sepracor*, 308 F. Supp. 2d at 34 (defendants obligated to "disclose known facts" about their drug application that "undermined their predictions of [the drug's] success"); *Regeneron*, 2005 WL 225288, at *18 (same).

In sum, Defendants' warnings "failed to correct the false impression created by the defendants' public statements or to supply the truth that they omitted." *Lormand*, 565 F.3d at 247. Accordingly, Genzyme's cautionary language failed to rendered its statements "immaterial as a matter of law," *Shaw*, 82 F.3d at 1211, and the PSLRA safe harbor does not apply.

E. Genzyme's Miscellaneous Materiality Arguments Are Meritless

Genzyme offers a variety of scattershot arguments to the effect that reasonable investors would not have found its statements to be material. These arguments can be swiftly rejected.

1. Defendants' Statements that Lumizyme Was On Track for Prompt FDA Approval Were Material

Genzyme contends (Br. at 26) that because PDUFA decision dates are subject to change, it was not reasonable for Plaintiffs to rely on its assurances of Lumizyme's approval. But Plaintiffs do not allege that the PDUFA "decision dates" were false. In fact, the FDA *did* reach decisions on the Lumizyme BLA by the February 28, 2009 PDUFA date (*i.e.*, a decision to withhold approval pending resolution of CGMP deficiencies, ¶112), and, later, by the November

14, 2009 PDUFA date (declining to approve the BLA due to unresolved CGMP deficiencies, ¶187). Defendants' fraud was not in stating that the FDA would reach *decisions* on the Lumizyme BLA by the PDUFA dates, but in falsely assuring that the FDA would *approve* it by those dates, given Defendants' knowledge of serious, unremedied compliance problems at Allston that effectively precluded FDA approval by the touted PDUFA dates. ¶¶100-02, 162. By repeatedly telling investors, *e.g.,* that approval was "expected" and that Genzyme was "confident" of quick approval, (¶¶217, 275, 297), Defendants "necessarily implied that there would be no serious impediments to timely FDA approval," and "[t]hus, Defendants' omission of facts suggesting a possible delay in approval was misleading." *Yanek*, 388 F. Supp. 2d at 1130; *see also Baron*, 285 F. Supp. 2d at 103 (disclosure is required if "omission of the information creates a materially false impression of the company's well-being").[53]

2. Defendants' False Statements that Genzyme Planned to Sell Lumizyme in the U.S. Were Material

Defendants assert that their internal, undisclosed decision to abandon plans to produce Lumizyme for commercial sale in the U.S was immaterial as a matter of law because Genzyme never abandoned its longer-term plans to seek FDA approval to make and sell the 4000L variant of the product in the U.S.[54] However, markets eagerly anticipated the Lumizyme launch because Defendants projected that significant revenues from U.S. Lumizyme sales would quickly follow. ¶¶52, 103, 164, 292. Genzyme's internal decision to abandon its plans to market Lumizyme meant that ***no*** form of mass-produced Myozyme would be available for sale in the U.S. until at

[53] *Dendreon* presents a useful contrast. There, as here, defendants did not disclose that they had received a Form 483, but – unlike Genzyme – the *Dendreon* defendants told investors only that there would be a *decision* on their new drug BLA by the PDUFA date. The court found that those much more limited statements were not misleading because "nothing in them states or suggests that Provenge is going to be approved (*which would tend to influence the value of the stock*)." 2008 WL 5130042, at *4 (emphasis added). Here, in contrast, Defendants repeatedly assured investors of Lumizyme's imminent *approval* – which plainly "tend[ed] to influence the value of the stock," given Lumizyme's importance.

[54] Investors knew all along that Genzyme eventually intended to seek approval of the 4000L product in the U.S. *See, e.g.*, Ex. AA, at 12 (transcript of July 2008 conference call). Nonetheless, Defendants repeatedly emphasized the importance of the Lumizyme (2000L) BLA – which signaled to investors that Lumizyme would be key revenue driver in the short term, even if 4000L was approved in the longer term.

least mid-2010, as that was the earliest date by which 4000L product could obtain FDA approval, even assuming (contrary to fact) that the Lumizyme BLA could be approved by November 2009. That decision also rendered patently false any projection that Genzyme would derive revenue from Lumizyme sales in 2009. At best, the decision would cost Genzyme at least two quarters' worth of Lumizyme revenue; indeed, when the decision was finally announced, Genzyme was forced to lower its revenue guidance for Myozyme-related revenue. ¶153. The decision also introduced a new layer of uncertainty as to when mass-produced Myozyme would be sold in the U.S., as everything now depended on the success of Genzyme's FDA application for the 4000L product, thus raising the prospect of even longer delays. ¶199. Finally, the decision was a further indication of problems at Genzyme's flagship Allston facility.

Such facts are not "so obviously unimportant to a reasonable investor that reasonable minds could not differ" as to their importance. *Bond Opp. Fund II, LLC v. Heffernan*, 340 F. Supp. 2d 146, 159 (D.R.I. 2004). Indeed, their materiality is confirmed by the fact that Genzyme's stock price fell 8.4% when its true plans were revealed. ¶160. *See also Am. W.*, 320 F.3d at 935 (stock price movements are indicative of materiality).

3. Genzyme's Statements Were Not Puffery

Certain vague statements may be deemed "puffery" that is immaterial as a matter of law. *Suna v. Bailey Corp.*, 107 F.3d 64, 72 (1st Cir. 1997). However, like all materiality issues, "puffery" determinations are fact-intensive and can be made on a motion to dismiss only when the statements "are so obviously unimportant" that reasonable minds cannot differ as to their importance. *Bond Opp. Fund II,* 340 F. Supp. 2d at 159; *In re Globalstar Sec. Litig.*, 2003 WL 22953163, at *8 (S.D.N.Y. Dec. 15, 2003). Even "soft" statements are actionable, as when defendants "issue statements calculated to mislead investors by couching them with glowing yet relatively vague language, knowing full well that the investing public would attach to them meanings inducing them to invest in a corporation they otherwise would avoid." *In re Midlantic Corp. S'holder Litig.*, 758 F. Supp. 226, 232 (D.N.J. 1990). As the Supreme Court has also

explained, "conclusory" terms like "high" or "fair," when used in a commercial context, are "reasonably understood to rest on a factual basis that justifies them as accurate, the absence of which renders them misleading." *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1092-93 (1991). Thus, courts routinely hold that "where a defendant affirmatively characterizes management practice as 'adequate,' 'conservative,' 'cautious,' and the like, the subject is 'in play.'" *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 281-282 (3d Cir. 1992); *see also Novak v. Kasaks,* 216 F.3d 300, 315 (2d Cir. 2000) (statements such as "in good shape" or "under control" are actionable if false).

To determine whether statements are inactionable puffery, they "must not be assessed in a vacuum (i.e., by plucking the statements out of their context to determine whether the words, taken per se, are sufficiently 'vague' so as to constitute puffery).... The statements are properly interpreted only by reference to the relevant circumstances that underlie their meaning." *Scritchfield v. Paolo*, 274 F. Supp. 2d 163, 175-76 (D.R.I. 2003); *see also Casella v. Webb*, 883 F.2d 805, 808 (9th Cir. 1989) ("What might be innocuous 'puffery' or mere statement of opinion standing alone may be actionable as an integral part of a representation of material fact when used to emphasize and induce reliance upon such a representation."). Thus, for example, in *In re Allaire Corp. Sec. Litig.*, 224 F. Supp. 2d 319 (D. Mass. 2002), the court held that the defendant's representation that a new product was "fueling growth" was actionable, because it was "a precise statement as to the basis for profit growth." *Id.* at 331-332.

Here, none of Defendants' statements were mere "puffery," as they were all clearly designed to convey meaningful (but false) assurances concerning conditions at Genzyme's most important facility (Allston) and the status of its most important and highly touted new product (Lumizyme). For example, when Termeer told investors that Genzyme was in a "robust position to meet that projection," he was not speaking in the abstract; he was specifically referring to the Company's ability to meet earnings projections that included revenues from U.S. sales of Lumizyme. ¶254. Similarly, Termeer's April 2009 statement that Genzyme was being managed

in a "conservative way" (¶292), was the basis for his contention that it would meet earnings forecasts that depended on sales of Fabrazyme, Cerezyme and Myozyme/Lumizyme – even though Genzyme by that time had internally decided it would not be producing Lumizyme for commercial sale, and had taken very serious risks by (a) running the aging Allston plant at "over 100% capacity" in the face of "systemic and fundamental" compliance deficiencies, while having simultaneously (b) allowed its inventories of Cerezyme and Fabrazyme to be drawn down. ¶¶83-84, 99. *See, e.g.*, *Serabian*, 24 F.3d at 364 (statements that company practice was to "address issues in a timely and conservative manner" and "worked from very conservative assumptions" were actionable).

The same is true of the remaining statements Genzyme challenges as puffery. *See, e.g.*, ¶263 ("growth potential for this segment remains strong" refers specifically to LSD segment, whose drugs were produced at the faltering Allston plant); ¶237 & McLaughlin Dec. Ex. Z (statement that Genzyme had "set in place a number of catalysts that will drive near-term growth," and listing the expected approval of Lumizyme as one such catalyst). These are precisely the kinds of statements that courts find both material and actionable. *See, e.g., Amgen*, 544 F. Supp. 2d at 1027 (characterizing drug as having "strong growth potential" is not puffery).[55] As stated in *Sepracor*, although "[i]n certain circumstances, vague statements expressing confidence in a product's potential" are puffery, "such a conclusion is not possible" where defendants tout the potential of a new drug that they know cannot meet FDA requirements for approval. 308 F. Supp. 2d at 33.

[55] *See also Freudenberg v. E*Trade Fin. Corp.*, 2010 U.S. Dist. LEXIS 46053, at *43 (S.D.N.Y. May 10, 2010) ("we enter 2007 ideally positioned to capitalize on secular growth trends in the industry" was actionable as misrepresentation of existing fact); *Darquea v. Jarden Corp.*, 2007 U.S. Dist. LEXIS 40247, at *13 (S.D.N.Y. May 31, 2007) (sales are going "just fine"); *In re AOL Time Warner, Inc., Sec. & ERISA Litig.*, 381 F. Supp. 2d.192, 221 (S.D.N.Y. 2004) ("Our businesses are doing great. I want to assure you we gave The Street our guidance and we are sticking to it. Period."); *Manavazian v. Atec Group*, 160 F. Supp. 2d 468, 474 (E.D.N.Y. 2001) ("poised for future growth," "positioned . . . for dramatic revenue and earnings growth," and "still on track" to meet earnings and growth models); *In re Computer Assocs. Class Action Sec. Litig.*, 75 F. Supp. 2d 68, 73 (E.D.N.Y. 1999) ("business fundamentals are strong").

F. Loss Causation

Loss causation is the "causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341 (2005). "[T]o properly plead loss causation, a plaintiff must allege 'that the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security.'" *In re TyCom Ltd. Sec. Litig.*, 2005 U.S. Dist. LEXIS 19154, at *40 (D.N.H. Sept. 2, 2005) (quoting *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005)). Loss causation need only be pled in accord with Rule 8(a). *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 256 (D. Mass. 2006).

Genzyme (Br. at 50) only challenges loss causation with respect to statements regarding its intention to market Lumizyme commercially in the U.S. However, the Complaint properly alleges that Genzyme (1) had secretly decided *not* to market Lumizyme in the U.S. in March 2009, ¶199, but (2) only publicly disclosed this fact on July 22, 2009, ¶153, at which point (3) the price of Genzyme shares fell sharply. ¶160. In sum, Plaintiffs allege that Defendants "concealed something from the market," i.e., that Lumizyme revenues would not be forthcoming (and that Allston lacked capacity to handle the demands of Lumizyme manufacture), and that when this information was disclosed it "negatively affected the value of the security."

Genzyme nonetheless claims there is no loss causation because Termeer did not *admit* until December 2009 (post-Class Period) that Genzyme's decision to abandon U.S. production of Lumizyme had been made in March 2009. Genzyme Br. at 50-51. Thus, Genzyme contends that there is no loss causation until a defendant admits that a prior non-disclosure was *fraudulent.* Such arguments are routinely rejected, as they would preclude §10(b) claims absent an admission of fraud. *See, e.g., In re Credit Suisse-AOL Sec. Litig.*, 465 F. Supp. 2d 34, 46-47 (D. Mass. 2006) (explicit disclosure of fraud is sufficient, *but not necessary*, to allege loss causation); *In re Parmalat Sec. Litig.*, 375 F. Supp. 2d 278, 307 (S.D.N.Y. 2005) (same).

G. Plaintiffs Do Not Rely on "Group Pleading"

The Individual Defendants (Br. at 3-7) make much ado about whether the group pleading doctrine applies. This is a pleading presumption that statements in "registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company." *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d 621, 637 (S.D.N.Y. 2008). The presumption exists because a plaintiff is unlikely to know, prior to discovery, which insiders were responsible for which documents. *Degulis v. LXR Biotechnology*, 928 F. Supp. 1301, 1311-12 (S.D.N.Y. 1996).

Here, the group pleading doctrine has at best a minimal role, because each Defendant personally made false statements and/or material omissions, and thus there is no need to "infer" that they made statements for §10(b) purposes. Several of them signed corporate documents, and thus are deemed to have "made" any false statements contained therein. *See, e.g.*, *Cabletron*, 311 F.3d at 41. For example, Termeer and Wyzga signed Genzyme's SEC filings (and accompanying Sarbanes-Oxley certifications), which contained materially false and misleading representations. ¶¶25, 27, 225, 234, 240, 257, 283, 298, 319, 361. Each Individual Defendant also personally made false oral statements, whether in analyst conference calls, press interviews, or as quoted in written press releases.[56] Moreover, although Defendants argue that they cannot be responsible for each other's oral statements, Plaintiffs allege that each of the Individual Defendants sat silently on conference calls when the others made false oral statements, *see, e.g.*, ¶¶217, 221, 230, 232, 267, 273, 276, 288 – and each is thus primarily liable for failing to correct the misstatements of others during those calls. *See Barrie v Intervoice-Brite*, 409 F.3d 653, 655 (5th Cir. 2005) (high ranking company officials "cannot sit quietly at a conference with analysts, knowing that another official is making false statements, and hope to escape liability for those

[56] *See* ¶¶217, 219, 223, 230, 237-39, 249, 251, 267, 276-77, 292, 304-05, 316, 318 (Termeer); ¶¶217-18, 230, 238, 251, 266, 268-69, 275-76, 292, 304, 316, 318 (Wyzga); ¶¶217, 230, 251, 304, 316, 318 (Meeker); ¶¶230, 246, 255, 271, 276-80, 292, 294-95, 297, 304-09, 316 (Lawton); ¶¶238, 268, 270-71, 276, 280, 292-93, 296, 304, 312-14, 316, 318 (McDonough); and ¶¶276, 281, 282, 289, 304 (Bamforth).

statements. If nothing else, the former official is at fault for a material omission in failing to correct such statements in that context"); *Dendreon*, 2008 WL 5130042 at *8 (same).[57]

H. Plaintiffs State Valid Claims Under §20(a)

Section 20(a) of the 1934 Act imposes liability on persons who "directly or indirectly, control[] any person liable" under §10(b), "unless the controlling person acted in good faith." 15 U.S.C. § 78t(a). To state a §20(a) claim, Plaintiffs need only plead (1) a violation of §10(b) by the controlled entity, Genzyme; and (2) control of Genzyme by the §20(a) defendant. *Stone & Webster*, 414 F.3d at 194 (§20(a) "does not ... obligate the plaintiff to plead or prove scienter (or any other state of mind) on the part of the controlling persons named as a defendant;" instead, the defendant may establish an affirmative defense "by proving that he or she acted in good faith and did not directly or indirectly induce the act or acts constituting the violation"). Plaintiffs, as the Individual Defendants concede (Br. at 23), may establish control by pleading a person's active involvement in the controlled entity's overall management, policy-making and operations, *or* by alleging control over the entity's offending statements. *See also Aldridge*, 284 F.3d at 85. Moreover, §20(a) claims are evaluated under Rule 8(a)'s notice pleading standard. *Teamsters Local 617 Pension and Welfare Funds v. Apollo Group, Inc.*, 690 F. Supp. 2d 959, 970 (D. Ariz. 2010); *Cornwell v. Credit Suisse Group*, 689 F. Supp. 2d 629, 638 (S.D.N.Y. 2010); *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, 2005 WL 2148919, *7 & n.95 (S.D.N.Y. Sept. 6, 2005) (noting that this is the majority view).[58] Thus, Plaintiffs need only create a "reasonable inference" of control. *Quaak v. Dexia, S.A.*, 445 F. Supp. 2d 130, 148 (D. Mass. 2006) (*quoting Cabletron*, 311 F.3d at 41). Plaintiffs easily meet that standard here.

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[57] Although Plaintiffs need not rely on the group pleading doctrine and the issue is thus largely moot, the Individual Defendants' assertion (Br. at 4) that it has been superseded by the PSLRA is incorrect. *See, e.g., In re Tyco Int'l, Ltd.*, 2004 WL 2348315, at *2 (D.N.H. Oct. 14, 2004) ("group pleading" doctrine is not inconsistent with the PSLRA); *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d 131 (D. Mass. 2001) (post-PSLRA case applying group pleading doctrine).

[58] Genzyme argues that *Swack v. Credit Suisse First Boston*, 383 F. Supp. 2d 223 (D. Mass. 2004), requires control to be pled under Rule 9(b). In *Swack*, plaintiffs made no allegations *at all* concerning a particular defendant's "control," and held only that a plaintiff must make some effort to plead control – without deciding whether Rule 8(a) or 9(b) governed. *Id.* at 246.

First, each Individual Defendant had control over multiple false or misleading statements, as each (by signing SEC filings and/or speaking on conference calls) *personally made* – and therefore caused Genzyme to make – such statements. This alone pleads §20(a) violations.[59] *See Chalverus v. Pegasystems, Inc.*, 59 F. Supp. 2d 226, 236-37 (D. Mass. 1999) (courts "should deny a motion to dismiss a §20(a) claim when the defendants themselves made the allegedly false and misleading statements") (citing *In re PLC Sys., Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 122 (D. Mass. 1999); *In re Lernout & Hauspie Sec. Litig.*, 208 F. Supp. 2d 74, 90-91 (D. Mass. 2002) (same); *Gelfer v. Pegasystems, Inc.*, 96 F. Supp. 2d 10, 18 (D. Mass. 2000) (same).[60]

Second, a company's top officers are deemed to control their company by virtue of their positions. *In re Alstom, SA, Sec. Litig.*, 406 F. Supp. 2d 433, 488, n.51 (S.D.N.Y. 2005) ("The CEO ... presumably has the power to control a corporation."); *In re StockerYale Sec. Litig.*, 453 F. Supp. 2d 345, 361 (D.N.H. 2006) (plaintiffs adequately alleged facts showing control by CFO due to involvement in issuance of statements at issue); *In re Sys. Software Sec. Litig.*, 2000 U.S. Dist. LEXIS 3071, *53-54 (N.D. Ill. Mar. 8, 2000); *In re Next Level Sys. Sec. Litig.*, 1999 U.S.

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[59] The Individual Defendants also seem to imply that plaintiffs' §20(a) claims must fail absent a showing that each such defendant controlled the conduct of each of the other Individual Defendants. *See* Indiv. Def. Br. at 23 ("Despite relying on many oral statements of particular individuals, Plaintiffs plead no facts plausibly suggesting that the other five defendants were exercising any control over those statements."). This is a red herring, as Plaintiffs do not allege that the Individual Defendants controlled *each other*, but rather that each controlled *Genzyme*, and had the power to prevent the issuance of Genzyme's false statements, to correct them, and/or to disclose concealed information earlier. ¶¶359-62.

[60] The Individual Defendants' cases are distinguishable or not on point, as none address the sufficiency of allegations against top executives who were alleged to have actually made false and misleading statements. *See In re Lernout & Hauspie Sec. Litig.*, 286 B.R. 33 (D. Mass. 2002) (discussing requirements for pleading "control" against outside director and audit committee member); *Aldridge*, 284 F.3d at 75 n.1 & 85 (addressing sufficiency of allegations against trusts that were passive shareholders and happened to own a majority of the defendant company's shares, and reinstating § 20(a) claims against individual defendants who were "members of the [company's] management team"); *In re Credit Suisse-AOL Sec. Litig.*, 465 F. Supp. 2d at 60-61 (addressing defendants' control over employees, rather than corporation, and finding control adequately alleged); *Sheinkopf v. Stone*, 927 F.2d 1259 (1st Cir. 1991) (addressing liability of law firm for a real estate company formed by one of its employees); *Rand v. M/A-COM, Inc.*, 824 F. Supp. 242 (D. Mass. 1992) (at summary judgment, discussing liability of defendant who played no role in making any allegedly false statements).

Dist. LEXIS 5653, *34 (N.D. Ill. Mar. 31, 1999).[61] The inference is particularly apt here, where each Individual Defendant is one of the Company's top three officers (Termeer, Wyzga and Meeker) or the head of regulatory affairs (Lawton) or the head a division responsible for the key products or production facilities at issue (Bamforth and McDonough). ¶¶25-30.

Because "culpable participation" is not an element of a §20(a) claim (and defendants' purported good faith conduct is instead only an affirmative defense), the majority of courts – including five Courts of Appeals and at least one court in this District – do not require plaintiffs to plead culpable participation.[62] Nor, as the Individual Defendants contend (Br. at 24-25), do *Iqbal* or *Twombly* somehow raise the bar to require allegations of culpable participation, because alleging a "plausible" claim in no way requires Plaintiffs to negate an affirmative defense. *See Davis v. Indiana State Police*, 541 F.3d 760, 763 (7th Cir. 2008).

In any event, even if "culpable participation" were required, "[t]he seminal case adopting the 'culpable participant' requirement equates culpable participation with lack of good faith." *Alvarado*, 448 F. Supp. 2d at 339 (*citing Lanza v. Drexel & Co.*, 479 F.2d 1277, 1299 (2d Cir. 1973)); *see also In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 395-96 & n.125 ("culpable participation" may mean only negligence; §20(a) has no scienter element).[63] Here,

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[61] The allegations here are substantially more detailed than those in the cases cited by the Individual Defendants. *Cf. In re Digital Island Sec. Litig.*, 223 F. Supp. 2d 546, 561-63 (D. Del. 2002) (allegations regarding defendant's control were defective, as they merely restated legal standard for control person liability); *Teamsters Local 617 Pension and Welfare Funds v. Apollo Group, Inc.*, 690 F. Supp. 2d at 979 (given lack of allegations regarding defendant's responsibilities as president, court could not determine whether or not "he was simply a titular President").

[62] *See, e.g., Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083, 1108-09 (10th Cir. 2003); *Brown v. Enstar Group, Inc.*, 84 F.3d 393, 396 (11th Cir. 1996); *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1575 (9th Cir. 1990); *Metge v. Baehler*, 762 F.2d 621, 631 (8th Cir. 1985); *G.A. Thompson & Co. v. Partridge*, 636 F.2d 945, 958 (5th Cir. 1981); *Brooks Automation,* 2007 WL 4754051, at *13-14. Numerous district courts in other Circuits have followed the same approach. *See, e.g., In re Huffy Corp. Sec. Litig.*, 577 F. Supp. 2d 968, 1021 n.56 (S.D. Ohio 2008); *Able Labs.*, 2008 WL 1967509, at *29; *In re Proquest Sec. Litig.*, 527 F. Supp. 2d 728, 746 n.10 (E.D. Mich. 2007); *In re Parmalat Sec. Litig.*, 497 F. Supp. 2d 526, 532 n.42 (S.D.N.Y. 2007); *In re MicroStrategy, Inc. Sec. Litig.*, 115 F. Supp. 2d 620, 659 (E.D. Va. 2000).

[63] As noted in *In re WorldCom, Inc. Sec. Litig.*, 294 F. Supp. 2d 392 (S.D.N.Y. 2003), "if §20(a) contained the requirement that scienter be pleaded and proved, there would be little purpose served by §20(a) since a defendant who acts with scienter is liable under §10(b)." *Id.* at 420, n.18.

because Plaintiffs adequately allege the Individual Defendants' scienter for purposes of their §10(b) claims, *a fortiori* they have more than adequately alleged their "lack of good faith." *See In re Global Crossing Ltd. Sec. Litig.*, 2006 WL 1628469, at *11 (S.D.N.Y. June 13, 2006) – and indeed, the fact that each Individual Defendant made oral false statements and/or signed false SEC filings alone suffices to satisfy any culpable participation requirement that may exist. *Fox v. First BanCorp*, 2006 WL 4128534, at *8 (D.P.R. Nov. 6, 2006).

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss should be denied.

DATED: August 6, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Peter A. Pease, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on August 6, 2010.

Dated: August 6, 2010

/s/ Peter A. Pease
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